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INTERIM PERFORMANCE EVALUATION OF THE PROMOTING THE QUALITY OF MEDICINES (PQM) PROGRAM

August 2018

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Cover Photo: Department of Food and Drug Administration staff are trained on high-performance liquid chromatography at the Pharmaceutical Chemistry Laboratory in Nay Pyi Taw, Burma. Credit: Dr. Lu Lu Kyaw Tin Oo.

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ABSTRACT

The Promoting the Quality of Medicines (PQM) program, a USAID cooperative agreement (2009–2019) with the United States Pharmacopeial Convention, a nonprofit organization, aims to help assure the quality, safety, and efficacy of medicines of relevance to USAID health programs. It is the Agency's response to the growing development challenge posed by substandard and falsified medicines worldwide.

The purposes of this interim evaluation were to determine the effectiveness of PQM's implementation in achieving the program goal and intermediate results, and to provide prioritized recommendations that can be feasibly incorporated into the remainder of the existing program.

The evaluation team used qualitative and quantitative data collection methods and analysis methods, including document reviews, online surveys, and in-person and remote interviews, and site visits to PQM programs in Indonesia, Nigeria, and Ethiopia.

Important outcomes of PQM's work were identified in strengthening medicines quality assurance systems and increasing the supply of quality-assured priority global health medicines. While the program faced and successfully addressed many management and technical challenges as it grew in size and complexity over its first eight years of implementation, these challenges at times affected its ability to devote time to effectively communicate its goal, technical approaches, and achievements to clients and stakeholders.

The evaluation team had four recommendations for PQM: develop a comprehensive and strategic communications strategy; continue to develop the results framework with a pathway of change; focus on implementation of the information management component of the knowledge management strategy; and adopt and integrate systems thinking and system theory approaches.

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¹ The term “health element,” as used in this report refers to the health program areas and elements defined in the Foreign Assistance Standardized Program Structure and Definitions. It includes HIV/AIDS, tuberculosis, malaria, and maternal and child health. <https://www.state.gov/f/indicators/>.

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ACRONYMS

AOR	Agreement Officer's Representative
API	Active pharmaceutical ingredient
CAPA	Corrective Action Preventive Action
CePAT	Center for Pharmaceutical Advancement and Training
CLM	Collaborative Learning Model
DQI	Drug Quality and Information
EAC	East African Community
FMHACA	Food, Medicines, and Health Care Administration and Authority (Ethiopia)
FPP	Finished pharmaceutical product
GDF	Global Drug Facility
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GHP	Global Health Programs Division (United States Pharmacopeial Convention)
GHSC-PSM	Global Health Supply Chain Procurement and Supply Management
HQ	Headquarters
IO	Intermediate objective
IRs	Intermediate result
ISO	International Organization for Standardization
KM	Knowledge management
LMICs	Low- and middle-income countries
M&E	Monitoring and evaluation
MNCH	Maternal, neonatal, and child health
MQDB	Medicines Quality Data Base (United States Pharmacopeial Convention)
MQM	Medicines Quality Monitoring
MRIS	Medicines registration information system
MTaPS	Medicines, Technologies, and Pharmaceutical Services program
NAFDAC	National Agency for Food and Drug Administration and Control
NDQCL	National and sub-National Drug Quality Control Laboratories
NMRA	National Medicines Regulatory Authority
NTD	Neglected tropical diseases
OEM	Original equipment manufacturing
OHS	Office of Health Systems
ORS	Oral rehydration salts
PMI	(U.S.) President's Malaria Initiative
PMS	Post-market surveillance
POUZN	Point-of-Use Water Disinfection and Zinc Treatment Project
PQ	Prequalification (World Health Organization)

PQM	Promoting the Quality of Medicines
QA	Quality assurance
QC	Quality control
QMS	Quality management system
RDQCL	Regional Drug Quality Control Laboratory
SF	Substandard and falsified (medicines)
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SOP	Standard operating procedure
SPSD	Standardized Program Structure and Definitions
SRA	Stringent Regulatory Authority
TB	Tuberculosis
UNCoLSC	United Nations Commission for Life-Saving Commodities for Women and Children
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organization
USFDA	United States Food and Drug Administration
USP	United States Pharmacopeial Convention
WHO	World Health Organization

EXECUTIVE SUMMARY

EVALUATION PURPOSE AND EVALUATION QUESTIONS

The purposes of this interim evaluation of the Promoting the Quality of Medicines (PQM) program were to:

1. Determine the effectiveness of PQM's implementation in achieving the program goal and intermediate results, including the ability to generate evidence that implementing its approach has contributed to strengthening quality assurance (QA) systems in low- and middle-income countries; the extent to which the management structure, processes, and staffing patterns have helped or hindered progress toward achieving the program goal and intermediate results; and the level of client satisfaction with progress toward achieving work plan objectives.
2. Provide prioritized recommendations that can be feasibly incorporated into the remainder of the PQM program.
3. Provide recommendations to USAID for potential future investments in medicines QA systems strengthening.

The evaluation posed five questions:

1. What is the effectiveness of the program's implementation of in-country (field support) work?
2. What is the effectiveness of the program's implementation of USAID/Washington-funded (directed core funds or health element²) work?
3. What is PQM's ability to demonstrate their work has contributed to the sustainable strengthening of medicines QA systems?
4. How well is PQM advancing the medicines QA agenda and providing global technical leadership in medicines QA?
5. How have PQM's management structure, processes, and staffing patterns helped or hindered progress toward achieving the program's goal and results?

PROGRAM BACKGROUND

PQM is USAID's primary mechanism to help assure the quality, safety, and efficacy of medicines of relevance to USAID health programs and the Agency's response to the growing development challenge posed by substandard and falsified medicines worldwide. PQM's goal is to strengthen QA systems to sustainably ensure the quality and safety of medical products and protect public health. It does this through implementing activities that will strengthen medical products QA systems, increase the supply of quality-assured medicines, and increase the utilization of medical product quality information for decision-making. PQM was originally awarded as a five-year cooperative agreement with the United States Pharmacopeial Convention in September 2009, with a \$35 million ceiling; a costed extension awarded in September 2014 increased this to \$110 million, and PQM, on schedule to reach its ceiling, is now scheduled to close on September 17, 2019. The program has received funding from all health elements, and USAID Mission funding represents 70 percent of all funding received to date.

² The term "health element," as used in this report, refers to the health program areas and elements defined in the Foreign Assistance Standardized Program Structure and Definitions. It includes HIV/AIDS, tuberculosis, malaria, and maternal and child health. <https://www.state.gov/f/indicators/>.

EVALUATION DESIGN, METHODS, AND LIMITATIONS

The evaluation team used a mix of qualitative and quantitative data collection and analysis methods, including document reviews; two online surveys (one for USAID Mission staff currently working with PQM or who recently worked with the program, and one for pharmaceutical manufacturers); and in-person and remote interviews with more than 50 key informants, including the PQM agreement officer's representative (AOR) team, health element teams from the USAID Bureau for Global Health, and global and regional stakeholders and partners and beneficiaries. In addition, site visits were made to three PQM country programs (Indonesia, Nigeria, and Ethiopia), where evaluators visited program sites and interviewed local counterparts and Mission staff. Data collection took place between October 2017 and January 2018. All data were triangulated at the analysis stage.

It was not possible to interview all PQM stakeholders, manufacturers, or Mission staff who have worked with PQM over its entire period of performance, and the three countries visited cannot be considered as representative of all countries that received technical assistance from PQM. These limitations were mitigated by including in the survey Missions that no longer receive assistance from the PQM program and Missions that currently work with PQM, and by reaching out to activity managers who have moved on to other Missions. However, the steps taken to minimize these limitations did not eliminate potential biases. Additional details on limitations are included in Section III.

FINDINGS, CONCLUSIONS, AND RECOMMENDATIONS

Evaluation Question I: What is the effectiveness of the program's implementation of in-country (field support) work?

PQM has been effectively addressing medicines quality issues by working closely with responsible government agencies and local stakeholders, using strategic approaches and appropriate technology. This is most notable in countries where PQM has had the opportunity to provide assistance over an extended period of time, such as Cambodia, Ethiopia, Indonesia, and Kenya. Assistance included support to local regulatory authorities, including transitioning from implementation of Medicines Quality Monitoring (MQM) activities that served to assess the quality of specific products (e.g., antimalarials) to building the post-market surveillance (PMS) function of National Medicines Regulatory Authorities (NMRAs) and helping them to take appropriate follow-up regulatory actions. In some cases, follow-up actions (e.g., recalls of poor-quality products) served as models for neighboring countries and influenced their regulatory decisions. However, such activities and their significance have not always been effectively communicated or documented in the countries where the work was being carried out, due to limited information-sharing practices in and between countries.

Even so, as PQM started to make gains in strengthening regulatory systems and information became more widely available about issues of poor drug quality (often identified through MQM activities), there was also a growing indication that the engagement of other stakeholders and sectors was needed for NMRAs to fully execute regulatory actions. In Greater Mekong Region, for example, implementation of PMS helped to identify the lack of importation controls and illegal drug markets as the main causes of falsified and substandard medicines in the market. However, the PMS data alone cannot solve problems if regulators, customs officers, police, and commercial entities do not collaborate. In Indonesia, for example, the NMRA expressed that it had reached the end of its sphere of action and influence, and that stopping the illegal trade of substandard and falsified medicines was not possible without the cooperation and collaboration of importation officials and the national police. Therefore, the evaluation team recommends that PQM continue to explore the value of multisectoral approaches to support for NMRAs to take appropriate follow-up regulatory actions.

PQM encountered various challenges working with manufacturers of finished pharmaceutical products (FPP) due to unexpected obstacles, many of which it was able to successfully address. In other cases,

PQM had to drop manufacturers from their planned activities after several months of technical assistance due to the need for additional capital investment to clear Corrective Action Preventive Action for Good Manufacturing Practices compliance, required for World Health Organization (WHO) prequalification (PQ). It is recommended that PQM consider conducting a detailed analysis of interventions with manufacturers to develop a framework to guide future planning and investment by defining potential barriers to market access. It is likely that the demand for assistance to manufacturers will only increase, particularly as African regional pharmaceutical manufacturing development initiatives are launched. Such guidance will help to identify technical assistance needs, including those that may be better addressed by other technical assistance entities, especially with respect to business development concerns.

One area for improvement is the strategic use of advocacy and communication to raise public awareness and to advocate for policy changes and increased support to NMRAs. The program description in the PQM extension document³ cites examples of how the program successfully used information, education, and communication techniques, especially public service announcements, in the Asia and Latin American regions to raise public awareness about issues of poor-quality medicines. PQM should consider reviewing these experiences to identify ways to give them new lives, either in different countries or by extending their reach in other ways.

Evaluation Question 2: What is the effectiveness of the program's implementation of USAID/Washington-funded (directed core funds or health element) work?

PQM's Washington-funded activities were found to be largely effective; they made important contributions to increasing the global supply of priority medicines for tuberculosis (TB), maternal, neonatal, and child health, and neglected tropical diseases (NTDs). Among these:

- Twenty TB products, including active pharmaceutical ingredients and FFP have obtained WHO PQ or Stringent Regulatory Authority (SRA) approval.
- The United Nations Commission for Life-Saving Commodities for Women and Children's reached its goal of having at least three manufacturers per QA commodity by 2015, with a total of 12 new manufacturers. PQM continues technical assistance to six new manufacturers of maternal, neonatal, and child health products.
- With PQM's technical assistance, four NTD products obtained WHO PQ or SRA approval. The program is engaged in technical assistance with 11 new manufacturers of NTD.
- PQM has provided important – and in many cases actionable – information about medicines quality that USAID, regulatory authorities, and researchers used to develop interventions.

The technical assistance provided by PQM is considered to be appropriate and of high quality. However, USAID health element teams and stakeholders, including manufacturers, expressed that they were not always clear on how program assistance was progressing, and the types and implications of specific challenges or barriers that the program was likely to encounter along the way to achieving results. The elaboration of an explicit strategy (including assumptions and measurable intermediate outcomes), especially for providing technical assistance to manufacturers, based on experiences to date that includes documentation of all steps taken, might have increased transparency and confidence in PQM's progress toward achieving intended outcomes. Having an explicit and detailed strategy, discussed in response to Question 3 as part of a theory of change, should also encourage more exploration around potential unintended effects and limitations of interventions.

³ PQM Modification #13, September 23, 2013.

Although USAID and stakeholders reported being satisfied with PQM's work, they also identified ways PQM staff could have been more effective. In particular, they felt that PQM should be more proactive with the analysis and use of data that was at its disposal and identify new opportunities or emerging issues instead of simply reporting on completed tasks.

PQM should also consider how it can have a greater impact by sharing its experiences to help bridge the silos that health element teams tend to have in their work environments. Although PQM does share with all the health elements their regular reports that include the complete portfolio of activities, this is a passive communication and clearly not sufficient to ensure that potentially useful and strategic information is communicated effectively and efficiently. PQM should ensure that staff have the opportunity and responsibility to ensure the effective flow of information under the new program management structure. Many of these issues can be addressed through a communications strategy and directly with the AOR team and the health element teams. (See response to Question 5.)

Evaluation Question 3: What is PQM's ability to demonstrate their work has contributed to the sustainable strengthening of medicines QA systems?

Much of PQM's work before 2015 was not systematically documented through a formalized monitoring and evaluation (M&E) system. The program updated its results framework in 2015 and is still in the process of deploying its new M&E system; however, the new results framework is not fully developed, lacking a narrative component⁴ to explain how PQM's activities contribute to the changes that will result in the sustainable strengthening of medicines QA systems. PQM program descriptions and briefs, and even the program description in the program extension document, elaborate successes and include several elements of what could be developed as a formal pathway of change.

Given the program's large size, the recognized importance of its work, and its growing visibility, PQM needs to consider how it can better demonstrate its value and "tell its story." For example, it will need to think beyond the typical "input – black box – output" paradigm⁵ to identify the most relevant and valid outcome measures.

The evaluation team encourages PQM to consider how outcomes can be described as components of the larger health system, and as having effects on issues of system feedback loops, governance, stewardship, financing, processes and flows of information, and stakeholder behavior. Identifying the potential positive and negative effects of PQM's work on the whole system, as well as limitations of its effect, will be imperative to fully understanding how its work contributes to strengthening health systems and provides essential information for scale-up, replication, and promoting sustainability. This exercise, which can be incorporated as part of the work plan development process, can also help USAID identify opportunities for optimal collaboration with complementary health systems strengthening technical assistance programs.

The evaluation team also encourages PQM to continue to develop the systems thinking and approaches underpinning its results framework. The WHO offers a robust and widely accepted "systems thinking" approach; based on its "Framework for Action,"⁶ which identifies six "building blocks" that make up health systems, it may help PQM align its activities and approaches (including justification) with other systems strengthening interventions. Once this framework has been adapted to the results framework, a

⁴ https://www.measureevaluation.org/prh/rh_indicators/overview/results-framework.html.

⁵ Ludwig von Bertalanffy, one of the founders of General System Theory, argued that the prevailing paradigm for scientific inquiry based on the Newtonian concept of closed systems and linear analysis did not consider a subject's surroundings, thereby creating a "black box" that obscures true nature of cause and effect. Ludwig Von Bertalanffy. *Perspectives on General System Theory: Scientific-Philosophical Studies* (1976).

⁶ World Health Organization. [Everybody's Business: Strengthening Health Systems to Improve Health Outcomes: WHO's Framework for Action](#). Geneva, WHO (2007). The six building blocks are service delivery; health workforce; information; medical products, vaccines, and technologies; financing; and leadership and governance (stewardship).

pathway of change can be developed. Annex IV provides useful tools to help with developing a theory or pathway of change.

Last, the WHO systems thinking approach offers PQM an appropriate framework upon which to build its interventions. It will help PQM build on the work of other health systems strengthening efforts, identify inherent risks within a health system, understand how its work interacts with the other building blocks of the system, and make clear its value-add to strengthening global QA systems.

Evaluation Question 4: How well is PQM advancing the medicines QA agenda and providing global technical leadership in medicines QA?

Many important program contributions are evident in the advancement of medicines QA. PQM's global technical leadership role has grown over time and is now well-recognized by stakeholders. However, there is a marked lack of agreement among global and regional stakeholders about what this role should be moving forward and how it should be carried out. For example, global and regional stakeholders value PQM staff presence at global and regional conferences and meetings, but they have noted that PQM was not present at a number of convenings where they believed it would have had a role. Furthermore, when present, staff representing the program were typically of mid-level rank. Several global and regional stakeholders said it would be desirable for both PQM staff and USAID to be present at such events. In addition, some national, regional, and global stakeholders identify PQM as an autonomous organization, and quite a number are unable to discern between PQM and the United States Pharmacopeial Convention (USP), and between USP and USAID or PQM and USAID. Similarly, although there are multiple examples of how PQM has been actively engaged with global and regional partnerships and initiatives, these partners and stakeholders perceive the program's level of engagement to be low, which also means that USAID's presence is perceived to be minimal. USAID should reflect on these entities' expectations, what role it would like to play within this context, determine the appropriate form of engagement, and work with PQM to communicate this to stakeholders accordingly.

As their roles and inter-relationships are largely unclear to stakeholders, PQM, USP, and USAID should develop a mutual understanding of how to address appropriate representation of one another at venues for technical or policy matters of regional and global dimensions. These issues can be addressed through a communications plan. The current plan needs to be further developed and implementation started. (See response to Question 5.)

Evaluation Question 5: How have PQM's management structure, processes, and staffing patterns helped or hindered progress toward achieving the program's goal and results?

PQM's management structure, processes, and staffing patterns changed over the period of performance in response to growing program management demands for more accountability and transparency that came with increased funding levels, more complex technical programming, and demands to open field offices. USP invested in strengthening finance and operations functions, as well as M&E and knowledge management (KM). Unfortunately, some of these changes came late in the program's period of performance.

With less than two years left in the program performance period, PQM should prioritize the full implementation of the M&E strategy, especially as it relates to the results framework. This experience can be useful to USAID, stakeholders, and other partners as they, too, strive to develop their corresponding frameworks.

In consultation with USAID, PQM should consider narrowing the scope of the KM strategy. A comprehensive KM strategy builds on a platform of information management that draws from an M&E system and other sources. The remaining program performance period is likely to be too short to fully

develop and effectively implement a comprehensive KM strategy. A more fruitful investment would be to complete the deployment of the Newdea online system for program management and M&E and focus on and finalize the information management element of the KM plan to optimally support a more comprehensive communications strategy.

The PQM communications strategy should be developed. It should more clearly and comprehensively define target audiences (e.g., USAID, stakeholders from other donor and multi-lateral organizations, and in-county counterparts), corresponding communication needs, and appropriate channels for that communication. Staff roles and responsibilities in the implementation of the strategy should also be clearly defined.

Last, as PQM further develops interventions and approaches to address issues of sustainability and potential scale-up, it should reconsider what might be the optimal staffing profile for both field offices and headquarters. For example, it may be able to identify opportunities to engage public health generalists to support activities that reduce current project management demands on highly specialized technicians or that do not require a specialist, such as coordinating activities with manufacturers.

KEY RECOMMENDATIONS

The evaluation team identified numerous examples of how PQM has been effective in addressing medicines quality issues. Since 2009, achievement of important outcomes can be tracked as interventions built upon the successes of previous interventions, leading to increasingly impressive results. However, PQM also faced several challenges as it grew in size and complexity, and has had some difficulty demonstrating effectiveness and “telling its story” of how its work has contributed to sustainable QA systems strengthening.

Below are the evaluation team’s four recommendations for PQM, all of which can be accomplished – and should be prioritized – within the relatively short remaining period of performance. These are followed by the team’s three recommendations for USAID.

Recommendations for PQM

Strengthen all aspects of communications

Many of PQM’s successes have not been well communicated or documented in a way that can be used to advocate for continued support for strengthening medicines regulatory systems. Familiarizing stakeholders through active communication about PQM, its mission, and operations, including successes and challenges, is urgently needed, as is advocacy for partnership support to maximize the program’s productivity and mission sustainability. USAID, national government, civil society, bilateral aid, and philanthropic and private sectors are among the groups indicated for targeted advocacy and communication work.

A more comprehensive PQM communications strategy is urgently needed. It should define who should be given specific information and for what purpose, when that information should be delivered and through what communication channels, and define staff roles and responsibilities. It should cover both internal and external clients and promote the active exchange of information.

Further develop the results framework and a corresponding pathway of change

USAID health element teams and global stakeholders have struggled to understand PQM’s specific activities, the rationale behind them, and how they help the program achieve its results. The lack of transparency regarding the processes and pathways of change leads to a “mystification” of PQM’s highly technical work. Adopting an explicit pathway of change or theory of change to clarify the processes that lead to results, including critical information on mediating variables that affect outcomes, will greatly aid PQM in demonstrating and communicating its value-add in terms of sustainability and QA systems strengthening within the context of the larger health system. With an overarching pathway of change to

guide the program, sub-pathways can be developed to support activities *within* and *between* each technical focus area (i.e., NMRA, National and sub-National Drug Quality Control Laboratories, and manufacturers).

The current PQM M&E system was launched only within the past year, and the KM plan was not fully developed at the time of data collection. Given the relatively short time remaining in the award, the evaluation team recommends that, in consultation with USAID, PQM should de-emphasize further development of the KM plan in favor of focusing on ensuring effective information management (a component of the plan) that will support the overall purpose of the communication plan. Updating the current results framework and developing the narrative pathway of change should occur simultaneously.

Continue to integrate genuine systems thinking and system theory approaches

The evaluation team recommends that PQM continue to integrate systems thinking and systems theory approaches/frameworks into the “fabric” of its work. Once this framework has been adapted to the results framework, a pathway of change can be developed. A pathway of change will not only help PQM understand its immediate impact but also how the effects of its work reverberate through the health system. As such, the pathway of change also serves as the framework for measurement of outcomes, processes, and contextual factors. Annex IV provides useful tools that can help with developing and incorporating a theory of change into PQM’s work. Last, the WHO’s systems thinking approach may help PQM identify stakeholders with which it may not have worked with previously.

Develop guidance for future investment in manufacturing

It is likely that the demand for assistance to manufacturers will only increase, particularly as African regional initiatives are launched. It is also likely that more stakeholders, observers, and sources for technical assistance will be engaged at different levels than in the past. Therefore, PQM should document its unique experience and further develop the approach to selecting and supporting manufacturers and contract research organizations for collaboration based on previous experiences as guidance and share this guidance with other entities that may be engaged in meeting the expected demand in assistance.

There is also a need to further develop the various tools individual staff use to establish an in-house, program-wide management tool to keep track of the technical support provided to manufacturers and per disease to monitor the progress, delays, and achievement of milestones. This tool can be included in the guidance document mentioned above. This will help PQM be more transparent and accountable in terms of documentation and actions regarding manufacturer “drop-out” or to help more rapidly identify when to “drop” a manufacturer, depending on the situation. This tool would not be part of the M&E system.

Having a clear market strategy that includes timely information about market access not only entices manufacturers to produce – it should also help to manage expectations for manufacturers’ return on investment. Although manufacturers are provided market data prior to assistance, they often need assistance to develop their own internal business case for engagement with PQM for technical assistance and for incurring expected costs. This is a technical need that is beyond PQM’s scope, but it may be included in the larger guidance document as a need that may be addressed by other entities that can provide this type of technical assistance.

Recommendations for USAID

Maintain level of engagement between the AOR team and PQM staff

PQM staff at all levels acknowledge the AOR team’s good communication and invaluable support. This includes providing information and guidance on USAID policies and priorities, as well as insights on interagency initiatives to combat falsified and substandard medicines.

Similarly, PQM has been able to share information about important developments in the field with the AOR team and support USAID's important role in the global arena with respect to high-quality medicines for public health. The benefits of this mutually supportive relationship cannot be overestimated and reflect the spirit of the cooperative agreement. However, for efficiency and effectiveness, the AOR must also interface between USAID teams and PQM on top-line matters of common vision and key outcomes/results.

Increase engagement with all health element teams

For several reasons, USAID health element teams tend to work in silos, which makes it difficult for relevant information to cross teams. PQM has not been immune to this challenge. Although some of the management changes at PQM are likely to help overcome the challenges of ensuring that strategic information is shared, the AOR team has proactively helped PQM by agreeing to support joint work plan reviews with health element teams. The AOR team should continue this approach, especially as health elements begin to focus on new opportunities through regional initiatives, including regional regulatory harmonization initiatives in Africa and Asia, and as technical issues arise that may require the technical inputs of other entities to address.

Increase presence at high-level global and regional stakeholder meetings

Although USAID is aware of the various global and regional initiatives regarding medicines quality and regulatory systems strengthening and is a well-recognized and a valued partner, it has been notably less present in important fora than its counterparts, including World Bank, WHO, the U.K. Department for International Development, the Swiss Agency for Development and Cooperation, the Norwegian Agency for Development Cooperation, and the European Union/European Commission, would like and expect. Although to some extent PQM can and does act as USAID's "eyes and ears," it does not have the authority to make any decisions about how the Agency should engage at the global level. USAID should be more present and be prepared to declare how it intends to contribute to ongoing and emerging initiatives.

I. INTRODUCTION

EVALUATION PURPOSE

This interim evaluation of the Promoting the Quality of Medicines (PQM) program has two purposes. First, USAID seeks to understand the extent to which PQM has been effective in achieving its goal and intermediate results. This includes assessing the ability to generate evidence that implementing its approach has contributed to strengthening quality assurance (QA) systems in low- and middle-income countries (LMICs); the extent to which the management structure, processes, and staffing patterns have helped or hindered progress toward achieving the program goal and intermediate results (IRs); and the level of client satisfaction with progress toward achieving work plan objectives. Second, the evaluation will provide USAID and PQM with prioritized recommendations that can be feasibly incorporated into the remainder of the program. The scope of work for this evaluation can be found in Annex I.

EVALUATION QUESTIONS

This evaluation posed five questions:

1. What is the effectiveness of the program's implementation of in-country work funded by local USAID Missions?
2. What is the effectiveness of the program's implementation of USAID/Washington-funded (health element) work?
3. What is PQM's ability to demonstrate their work has contributed to the sustainable strengthening of medicines QA systems?
4. How well is PQM advancing the medicines QA agenda and providing global technical leadership in medicines QA?
5. How have PQM's management structure, processes, and staffing patterns helped or hindered progress toward achieving the program's goal and results?

II. PROGRAM BACKGROUND

RESULTS FRAMEWORK

PQM is USAID's primary mechanism to help assure the quality, safety, and efficacy of medicines of relevance to the Agency's health programs and its response to the growing development challenge posed by substandard and falsified (SF) medicines worldwide. PQM's goal is to strengthen QA systems to sustainably ensure the quality and safety of medical products and protect public health. It does this through implementing activities designed to strengthen medical products QA systems, increase the supply of quality-assured medicines, and increase the utilization of medical product quality information for decision-making.

Award ID: GHS-A-00-09-00003-00
Award Date: September 18, 2009
Award Type: Cooperative Agreement, sole source
Performance period: 2009–2019
Ceiling: \$110 million
Implementer: United States Pharmacopeial Convention
USAID Office: Office of Health Systems

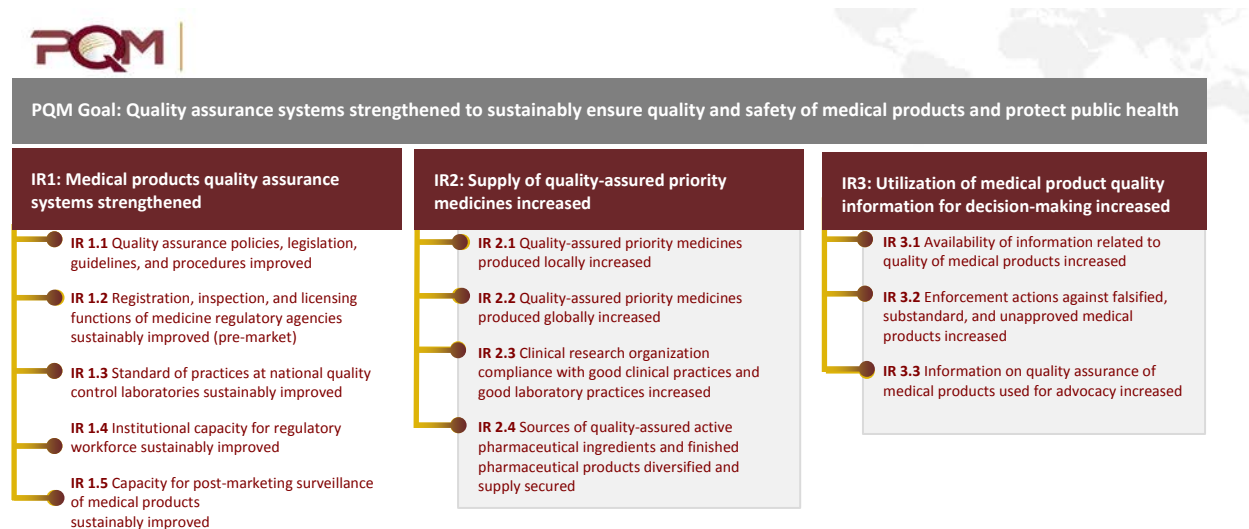
Initially, PQM's technical activities responded to a results framework defined by an overall objective to ensure the quality, safety, and efficacy of medicines of relevance to USAID health programs (Table 1). To do this, four intermediate objectives (IOs) and four IRs were provided, along with a list of illustrative activities. By 2013, when the extension was granted, the Office of Health Systems (OHS) had been established within the Bureau of Global Health and had absorbed PQM and other health systems programs. This presented an opportunity to develop a results framework to reflect the OHS priorities for providing models for sustainable systems strengthening.

Table 1. PQM Intermediate Objectives and Intermediate Results, 2009–2015

Overall Objective: To Ensure the Quality, Safety, and Efficacy of Medicines of Relevance to USAID Health Programs	
Intermediate Objectives	Intermediate Results
1. To strengthen national QA systems	1. More developing countries have a better functioning/fully operational medicines QA system in place
2. To increase the supply of good-quality medicines of direct relevance to priority USAID health programs	2. Increased availability of good-quality medicines of direct relevance to priority USAID health programs
3. To combat the availability of sub-standard and falsified medicines	3. Reduced presence of substandard and counterfeit medicines in the supply chain of developing countries
4. To provide technical leadership and global advocacy regarding the importance of medicines QA	4. Improved medicines QA tools and mechanisms, increased awareness of their importance, and increased funding for their implementation and use

By 2016, PQM developed the revised results framework, including the goal and IR areas (Figure 1), which elevates the goal of strengthening the pharmaceutical QA system in ways that promote sustainability. The biggest difference from the original framework was the creation of the new, more specific IR3, *Utilization of medical product quality information for decision-making increased*, replacing IO and IRs 3 and 4, and the provision of several sub-IRs as important elements for achieving higher-level results and outcomes. This is the framework that PQM is now using to guide programming.

Figure 1. PQM Results Framework, 2016–2019



PQM is the second in a succession of pharmaceutical product quality programs implemented by the United States Pharmacopeial Convention (USP) through cooperative agreements with USAID's Bureau for Global Health since 2000. Initially awarded to USP as a sole-sourced, five-year cooperative agreement in September 2009, the PQM award was based on the same rationale as predecessor programs that pointed to USP's unique status as an internationally reputable independent standard-setting organization with special status with respect to the U.S. Food and Drug Administration (USFDA).

SCOPE

PQM activities fall into three technical focus areas: strengthening National Medicines Regulatory Authorities (NMRAs); strengthening National and sub-National Drug Quality Control Laboratories (NDQCL); and strengthening pharmaceutical manufacturers (Table 2).

At the country level, support provided in one area can highlight the need for assistance in another, reflecting the interrelatedness of these technical areas.

Table 2. PQM Technical Focus Areas and Illustrative Activities

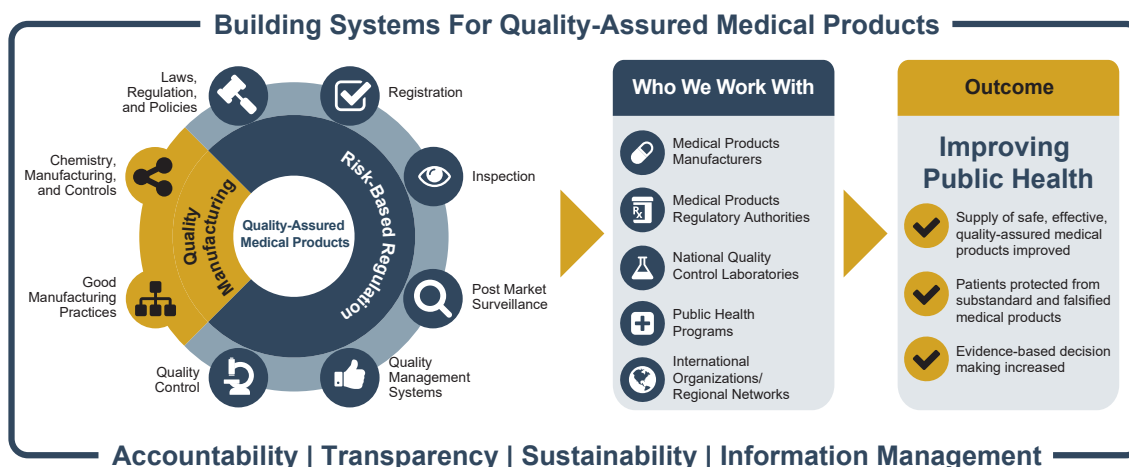
Strengthening National Regulatory Authorities	Strengthening Quality Control Laboratory	Strengthening Manufacturing
• Policies, laws, regulation reviews, revisions • Good practice/QA capacity • Dossier evaluation capacity • Facilities inspection capacity • Bioequivalence studies capacity • Post-marketing surveillance capacity	• QA management systems development • Analytical instrumentation provision and management • Support for achieving World Health Organization/ International Organization for Standardization (WHO/ISO) accreditation • Standard operating procedures (SOP) development and training	• Support for attaining Good Manufacturing Practices (GMP) • Chemistry and manufacturing controls capacity • Mock audits of facilities and documentations • Support for WHO/ISO accreditation • Reviews of dossiers in Common Technical Document format prior to submission

APPROACH

PQM uses six key characteristics to describe its overall approach to providing technical assistance: holistic; systems-based and sustainable; risk-based and pragmatic; in line with international standards;

collaborative; and informed by nearly 200 years of experience. This approach (Figure 2) has evolved during implementation and reflects lessons learned and emphasis on Agency strategic priorities at the time of PQM's extension into health systems strengthening, partnerships, science, and innovation.⁷

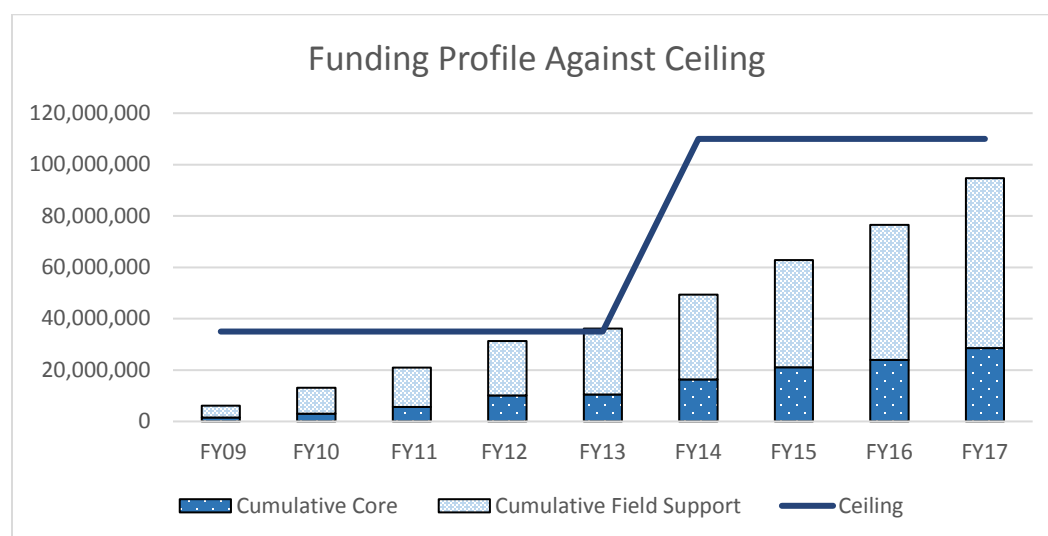
Figure 2. PQM's Technical Approach



FUNDING

When PQM was awarded in 2009, it had a \$35 million ceiling, which it was reaching in its fifth year of funding. A costed extension was awarded in September 2014, increasing the ceiling to \$110 million, in response to an unprecedented demand from USAID/Washington and Missions for uninterrupted and increased levels of PQM technical assistance to support existing and emerging national, regional, and global initiatives around medicines quality and regulatory systems strengthening. Currently in its ninth year, PQM is on schedule to reach its ceiling and will close in September 2019 (Figure 3).

Figure 3. PQM Funding 2009–2017



⁷ USAID's Strategic Health Framework 2012–2016: Better Health for Development. http://pdf.usaid.gov/pdf_docs/pdacu025.pdf.

PQM has received funding from all USAID global health elements, primarily for activities covered by IR2, *Supply of quality-assured priority medicines increased*. Health element funding represents approximately 30 percent of PQM funding, with most of that coming from tuberculosis (TB) (Table 3). Only 3 percent of total funding was provided to PQM for cross-bureau⁸ activities.

Table 3. Source of PQM Funding, 2009–2017

Source of Funding	Amount (\$)	Percent
Core health elements	25,558,000	27
TB	18,048,000	70
Maternal, neonatal, and child health (MNCH)	2,725,000	11
Neglected tropical diseases (NTD)	2,500,000	10
Malaria (President’s Malaria Initiative, PMI)	2,200,000	9
HIV	85,000	<.5
Cross-Bureau	2,969,195	3
Field	66,246,961	70
Total	94,774,156	100

Source: PQM funding profile, October 2017.

GEOGRAPHIC REACH

Since 2009, PQM has provided technical assistance to more than 34 countries, with field support from two regional and 29 country Missions.

⁸ Cross-bureau funding, formerly referred to as Common Agenda, includes health element funds received by OHS that are allocated to its programs to address health systems issues that are relevant to all elements.

III. EVALUATION METHODS AND LIMITATIONS

The evaluation team used a mix of qualitative and quantitative data collection and analysis methods, including document reviews, two online surveys (one for USAID Mission staff and one for pharmaceutical manufacturers), and in-person and remote key informant interviews (Annex II). Site visits were made to three PQM country programs (Indonesia, Nigeria, and Ethiopia), where evaluators visited program sites and interviewed staff from NMRA, NDQCLs, and manufacturers, as well as USAID Mission staff. Data collection took place from October 2017 to January 2018. All data were triangulated at the analysis stage.

Mission surveys. Surveys were distributed via SurveyMonkey to current and past PQM activity managers from 20 country Missions and two regional Missions; 17 of the country Missions and one regional Mission (18 Missions total) responded. Four of the 17 country Missions are no longer working with PQM but responded based on their past experiences. All responding Missions had at least three years of experience working with PQM.

The survey comprised 24 open- and closed-ended questions and captured four aspects of PQM's implementation: communication, quality of technical assistance and program management, overall performance toward IRs, and demonstration of important outcomes.

Responses were obtained from Mission activity managers working with PQM responsible for overseeing at least one in-country health element program. The total number of respondents was 26.

Manufacturer surveys. Surveys were sent to 45 manufacturers in 14 countries. Responses were received from nine manufacturers, two of which are no longer receiving assistance from PQM.

The survey comprised 15 open- and closed-ended questions and captured four dimensions of PQM's implementation: appropriateness or relevance of the type of assistance received for their goals, and the quality, amount, and timeliness of assistance.

Site visits. Two members of the evaluation team completed one-week site visits to PQM country programs in Indonesia, Nigeria, and Ethiopia. The agreement officer's representative (AOR) team selected the countries in advance based on the technical areas of in-country work and the current and historical size of PQM's budget in the country. These countries have PQM field offices and programs with varying degrees of complexity and maturity. PQM in-country staff and a local consultant facilitated interviews with local stakeholders and recipients of program assistance. In addition, the evaluation team leader conducted interviews in Geneva, Switzerland, with key informants at the Global Drug Facility (GDF) and WHO.

Interviews with key informants. Key informant interviews were conducted face-to-face, on Skype, or by phone. Face-to-face interviews were conducted with activity managers or Mission staff and manufacturers involved with PQM in visited countries. Some global stakeholders were interviewed in Geneva. Interviews with health element teams, all other global and regional stakeholders, and PQM partners were conducted remotely. Table 4 outlines the number of interviews completed by type of informant or informant group. In total, more than 50 people were interviewed. The list of people interviewed is presented in Annex III.

Interviews were semi-structured and lasted 45 minutes to one hour. Interviews captured three dimensions of PQM's implementation: quality and effectiveness of assistance or partnership, communication, and program management.

Document reviews. Program documents reviewed included annual work plans, quarterly and annual reports, and technical reports and publications, many of which are available on the PQM website (usp-pqm.org). External documents included USAID Bureau for Global Health program statements and reports, global and regional stakeholder documents, and information obtained from PQM and stakeholder websites. (See Annex III.) Documents were reviewed for evidence of appropriateness of technical activities and documentation of achievement of important outcomes.

Table 4. Number of Interviewees by Type

Types	No. of Interviews
AOR team staff	4
Country Mission staff	3
Health element teams staff	7
Manufacturer representatives	13
Global stakeholders/partners	20
Drug Regulatory Authority/Ministry of Health/NDQCL teams	8
PQM group meetings	4

Analysis. Program documents were reviewed within a matrix framework to ensure the systematic analysis of all relevant documentation. Interview data was thematically analyzed with NVivo® software. Survey data was analyzed to generate basic descriptive statistics. The results from all methods were then triangulated to ensure validity and reliability.

Limitations. It was not possible to interview all stakeholders or USAID Mission staff who have worked with PQM over the entire period of performance. This limitation was somewhat mitigated by including in the survey Missions that are no longer working with PQM. The generalizability of the findings to other Missions is limited because the evaluation team visited only three countries; however, survey data from Missions that were not visited are congruent with responses from the sites visited.

Survey response rates from manufacturers were low, due in large part to the outdated manufacturer point of contact list PQM provided the evaluation team. PQM was not always able to provide an alternative contact and in some cases the alternative point of contact had departed. Unlike the Mission surveys, it was not possible to follow up with points of contact who had ceased working at the manufacturer. The distribution of responses was also skewed toward Asian manufacturers; thus, generalizability to Africa and Central Asia is limited. However, the responses received from manufacturers were in line with manufacturer interview data.

IV. FINDINGS

EVALUATION QUESTION I

What is the effectiveness of the program's implementation of in-country (field support) work?

Overview

The primary goal of PQM's in-country (field support) work has been to ensure the quality and safety of medical products through strengthening QA systems in program countries. Most field-supported activities fall under IR1, *Medical products quality assurance systems strengthened*. PQM activities that contributed to IR2, *Supply of quality-assured priority medicines increased*, and IR3, *Utilization of medical product quality information for decision-making increased*, have also been funded with field support but are more often supported by Washington-based funding (via specific health elements).

PQM field-supported activities have varied based on the needs and the level of maturity of countries' QA systems. In some countries, PQM carried out activities responding to all IR1 sub-results areas, working closely with National Medicine Regulatory Authorities. IR1.1–1.5 activities that PQM implemented include improving legal framework on QA; strengthening regulatory functions to ensure quality of medical products before entry into the market; institutionalizing the standard of practices through ISO/International Electrotechnical Commission 17025 accreditation⁹ or WHO prequalification (WHO PQ)¹⁰ of NDQCLs; building institutional capacity for regulatory workforces; and strengthening capacity for post-market surveillance (PMS) of medical products.

In-country work under IR2 includes primarily IR2.1 and IR2.3, which address quality issues of locally produced and supplied medicines. The activities include assessing local manufacturers' QA systems to meet local GMP compliance requirements and providing quality management training and clearing Corrective Action Preventive Actions (CAPA) to achieve WHO PQ. PQM also provides technical support to contract research organizations to conduct bioequivalence studies for local manufacturers by improving Good Clinical Practices and Good Laboratory Practices.

In-country activities categorized under IR3 include working with NMRAs and NDQCLs to produce reliable information related to the quality of medical products and providing technical support to take regulatory enforcement actions based on evidence of drug quality. These actions also contribute to increased public awareness about SF medicines and spur GMP compliance through advocacy.

Appropriateness of technical assistance

The appropriateness of PQM's interventions was assessed in terms of the relevance and usefulness of activities from the perspective of the Missions and recipients of the assistance. Specifically, the evaluation team wanted to learn if the activities and approaches were appropriate given the specific country context and goals. Overall, the evaluation team found PQM's technical assistance to be highly appropriate.

There are several clear examples of how PQM interventions in one area led to interventions in other areas, causing a "domino effect" in important outcomes that could be interpreted as evidence of strengthening QA systems. For example, PQM assisted countries to improve pre-market assessment capacity (registration, licensing, and inspections) and risk-based PMS by focusing on priority medicines and priority or core regulatory functions while providing a roadmap for a fully functional pre-market assessment and PMS system. These improvements, even if limited, led to the creation of new medicines

⁹ General requirements for the competence of testing and calibration laboratories: <https://www.iso.org/standard/39883.html>.

¹⁰ WHO Prequalified Quality Control Laboratories: <https://extranet.who.int/prequal/content/medicines-quality-control-laboratories-list>.

quality-related policies/laws/regulations, as well as updates and improvements in existing regulatory frameworks in 11 program-supported countries, including changes to laws and policies that affect the entire sector. For example, in Nigeria, it used MNCH and malaria funds to work in close collaboration with the National Agency for Food and Drug Administration and Control (NAFDAC) to assess QA capacity, which led to the adoption of the National Quality Assurance Policy and guidelines in 2016.

Mission support was also used successfully to support in-country implementation of core health element initiatives (discussed in response to Evaluation Question 2). For example, with MNCH core funds, PQM developed the pharmaceutical monograph for chlorhexidine gel, which was subsequently provided to local pharmaceutical manufacturers in selected countries to increase the supply of quality-assured priority medicines. In the case of chlorhexidine, a locally produced product became available in Ethiopia, Kenya, Nigeria, and Pakistan.

In Ethiopia, the effort to improve the availability of quality-assured medicines required strengthening the QA system of the NMRA and assessing the status of local manufacturers, which led to the development of a GMP Roadmap. Both the government and the industry accept and own the roadmap as a means to improve local pharmaceutical manufacturers' GMP compliance. During a recent stakeholder meeting, PQM was identified as an important technical assistance provider in designing GMP facilities, Good Laboratory Practices, training for GMP compliance, and other QA system improvement areas.

"We gained our confidence in our test results after obtaining ISO certification with the support from PQM. Now we are not afraid to take regulatory actions even if we receive complaints on our test reports."

— NMRA Ethiopia

NMRAs, NDQCLs, and manufacturers consider the technologies that PQM introduced to be highly appropriate for the LMIC setting. Most notably, PQM's introduction of and training in Minilab™ technology was frequently mentioned as an appropriate intervention to support screening activities, especially where lab capacity in the field is limited.¹¹ The use of Minilab™ helped NDQCLs to understand the need to strengthen their screening activities in provinces where SF medicines are often found. It also helped to build analytical skills of lab analysts in provinces where training opportunities are more limited. Although many countries prefer to have a full-fledged quality control (QC) laboratory, even at the regional level, where the needs can be greater and more urgent, Minilab™ was eventually well accepted. Some countries even wanted to purchase more because they are easy to use and practical for priority and urgent needs. The use of Minilab™ was also well received by laboratory analysts for hands-on training.

Analysts from NDQCLs assessed the hands-on training provided by PQM as practical and striking the right balance between having an ideal situation and figuring out how to achieve the desired results given the reality of the work context. A senior laboratory manager in Nigeria said, "PQM has been very effective. We achieved ISO 17025 accreditation ... The trainer was wonderful. He knew how to teach in simple language and to combine the practical with the theoretical. The staff are very motivated now." Also, NDQCLs appreciated the training-of-trainers cascade approach to training. According to the senior management of the NDQCL in Indonesia, PQM had been effective, adding, "We are shifting from training of our staff to developing the capacity to do our own training. We have understanding now [of] what we need to do to keep staff well trained on standards."

In a few instances, Missions, government counterparts, and manufacturers questioned the program's approach. Two Missions stated their country counterparts had commented that PQM's activities seemed to promote a double standard in acceptable quality of medicines. It appears that in these instances, the Mission-supported activities focused on strengthening regulatory capacity while using core

¹¹ PQM notes that as per the risk-based PMS guidelines, screening technologies should be used as part of the Three Level Approach to identify gross poor-quality products and reduce the number of products that could be subjected to expensive compendial tests. So, even if lab capacity is available, not all samples should be subject to full confirmatory tests.

funds to support specific manufacturers to achieve WHO PQ. Local GMP standards and inspection requirements are often significantly less stringent than WHO PQ or international standards, and some manufacturers expressed frustration that PQM's activities created an "unfair situation" when the focus was only on the local market or when the manufacturers did not perceive any opportunity for competing on international tenders or exporting to other countries. According to PQM, however, its approach always advocates for established international standards, and local counterparts may not appreciate that their attainment is always "a work in progress."

The program encountered challenges working with manufacturers in countries with less mature pharmaceutical sectors. Some manufacturers felt frustrated because it took several months of program technical assistance for them to obtain a clearer picture of how much capital investment would be required to clear CAPA for GMP compliance to apply for WHO PQ. While PQM does discuss these issues with manufacturers before engaging in a formal relationship, many manufacturers reported that they did not fully understand the potential financial burden in the initial phase of engagement, and many had to drop from the assistance. This suggests that PQM's efforts to inform manufacturers was not always sufficient, and that these manufacturers might have benefitted from having additional assistance in business development, an area outside of PQM's technical mandate. On the other hand, in Nigeria, where there is a more mature pharmaceutical sector and a large domestic and promising regional market, manufacturers were very articulate about the calculus they needed to make to reach the decision of whether or not to work with PQM.

Quality of technical assistance

NMRAs, NDQCLs, manufacturers, and other counterparts assessed the quality of PQM technical assistance as very high. USP's international reputation and its close association with USFDA and WHO were important to recipients of assistance. Moreover, PQM staff and consultants were appreciated for the quality of their trainers, who were described as "knowledgeable and skilled," and dossier reviewers, who were seen as "thorough and supportive." Manufacturers in Indonesia and elsewhere have more confidence in their quality systems after participating in mock audits to prepare for official audits.

Strategic approaches

The scope of technical assistance for field support is generally determined by the availability of funds and funding priorities, both of which often change over time and are beyond the control of the program. This reality highlights the importance of having a guiding vision and strategic approaches to programming systems strengthening activities. However, a review of work plans from the first three years of implementation, along with interviews with PQM staff, indicate that in the early years of the program, entry points for engagement with NMRAs or NDQCLs were more opportunistic than deliberate or strategic. For example, PQM's Medicines Quality Monitoring (MQM) program began as a drug quality sampling activity aimed at gathering information that could be used to advocate for improving the quality of medicines, including strengthening regulatory systems; it did not include any *a priori* planning for sustainability or integration into an existing NMRA program. Over time, however, PQM was able to support the transition of the temporary and urgent needs-based MQM program to a more deliberate, periodic, and regular PMS program in 29 countries. Currently, 28 percent of the 229 PQM-supported sentinel sites have now completely transitioned to government-funded, -owned, and -sustained PMS programs and, in some countries, more sustainable PMS programs contributed to strengthening the pharmacovigilance system.

Several of PQM's malaria country programs followed an evidence-based approach that included using assessment results, audits, surveys, and knowledge of how regulatory systems operate to develop country-specific interventions.

"The priorities for PMI countries evolved over time. For example, in Liberia they started with only a small intervention [to get a law changed] and the country program grew from there, with interventions building on each other. This same approach was taken in other countries over time, like Ghana and Cambodia, and is considered to have been a very successful approach."

— PMI team

PMI's specific needs to safeguard its donations and minimize the risk of SF medicines in existing public and private sector supply chains and markets defined PQM's programmatic priorities.

Another example of program interventions evolving into more strategic approaches is the inclusion of NMRA staff in GMP inspections. Through this approach, PQM recognized the authority of NMRAs while providing practical hands-on experience with reputable experts, as well as valuable information about WHO prequalification requirements to manufacturers. With this experience in hand, NMRAs could see the opportunity to monitor the status of manufacturers with respect to compliance with international GMP standards, eventually leading to the creation of what is now known as the "GMP Roadmap."

"We learned the importance of GMP compliance in order to build production capacity of quality medicines through joint GMP inspections with PQM. That's why we developed GMP Roadmap to improve GMP compliance of all local pharmaceutical manufacturers."

— Ethiopian regulator

ISO accreditation or WHO PQ of NDQCLs was achieved in 20 program countries, with PQM supporting lab accreditation/reaccreditation or PQ/requalification 52 times (Table 4). Although obtaining ISO accreditation or WHO PQ was the goal in the beginning, the approach has become more broad-based, encompassing building the institutional capacity required for sustaining accreditation status. For example, rather than have QC laboratories focus only on conducting specific tests, staff are now learning how to develop their own SOPs on how to conduct those tests. In Nigeria, the institutionalized practices required for ISO accreditation motivated NDQCL staff to invest even further in developing their own continuous improvement tools, such as SOPs for laboratory practices. The central laboratory of NAFDAC, Yaba Laboratory in Lagos, Nigeria, has maintained accreditation and expanded the scope of pharmaceutical test methods from seven to 10.

"Obtaining ISO Certification was about changing our processes. We learned that we need to continuously improve our process by developing and implementing more SOPs as we understood the needs."

— Indonesian lab technician

Table 5. Number of Official Laboratories Supported by PQM

Year	Total	ISO Accredited							WHO PQ			
		Pharmaceutical		Medical Devices		Microbiology		Biologics	Pharmaceutical		Microbiology	
		A	RA	A	RA	A	RA	A	P	RQ	P	RQ
2010	3								2		1	
2011	1	1										
2012	1								1			
2013	3		1							1	1	
2014	8	5	1	1						1		
2015	7	2	3							1		
2016	10	4	4	1		1						
2017	19	2	6		2	3	1	1	1	1	1	1
TOTAL	52	14	15	2	2	4	1	1	4	4	3	1

Key: A=Accredited, RA=Reaccredited, P=Prequalified, RQ=Requalified

One of the more promising approaches for human resource development that PQM has adopted is the Collaborative Learning Model (CLM), a form of cascade training. CLM involves training staff from one laboratory to build the capacity, skills, and laboratory systems of another laboratory in the same country. For example, in 2015 the Yaba Laboratory achieved ISO 17025 accreditation with PQM support. Staff then set out to build the capacity, skills, and systems for Agulu and Kaduna Laboratories with no additional support from PQM. These laboratories attained ISO 17025 accreditation in September 2016 and March 2017, respectively, demonstrating the effectiveness of the CLM capacity

building approach to address ISO accreditation and WHO PQ requirements. Although a more formal evaluation of effectiveness not been conducted, PQM has determined that, based on this experience in Nigeria and a comparable experience in Burma, CLM is cost-effective because it requires only supervisory support after the initial training. In addition, PQM believes that it has increased the levels of confidence and motivation of those who train their colleagues, a perception shared by the lab management and staff. The model is expected to significantly contribute to the sustainability of the QA workforce as peers from neighboring laboratories can provide training for newcomers and mitigate the risks involved with high turnover rates.

“PQM has been able to train our lab staff in one year and obtain accreditation. It is remarkable! I know that it took another lab four years of assistance from another entity before they achieved accreditation. PQM did it in one. And, very importantly, PQM has turned my staff around — they have been very positively affected.”

— Senior lab manager, Yaba Laboratory
Nigeria

Strategic solutions also emerged from necessity. For example, in Cambodia and Senegal, where information-sharing among agencies is not common practice, PQM has shared findings about SF products with interministerial committees rather than individual agencies to ensure that the information would be made available to all relevant stakeholders and that more appropriate coordinated actions could be taken. In Cambodia, a PQM-supported MQM activity identified illegal drug outlets that the Cambodian Department of Drugs and Food shared with the appropriate authorities through the interministerial committee, which then mobilized to close all illegal drug outlets by December 2011. Unfortunately, PQM has not yet fully documented the effectiveness of these experiences.

To fully address the sustainability of results, it is clear that PQM will have to address the issue of access to financial resources. For example, to facilitate training activities and to help NDQCLs and NMRAs meet ISO accreditation and WHO PQ requirements, PQM has been providing reagents, reference standards,¹² and documentary standards. However, lab managers in Indonesia, Nigeria, and Ethiopia noted that these resources were also needed for lab functions beyond PQM activities and that they did not have the mechanisms and financing to replenish reference standards and regularly update pharmacopeia. A comprehensive systems strengthening approach should include addressing such concerns about financial sustainability.

Where PQM has provided sustained and continuous technical assistance over a relatively long period, with interventions linking to each other, important achievements can be identified and described in terms of institutional capacity building and sustainability. In Ethiopia, for example, where PQM has supported the regulatory authority since 2010, program efforts can be linked to important achievements of the NMRA and the Food, Medicines, and Health Care Administration and Authority (FMHACA). Figure 4 shows the support PQM provided to FMHACA and the administration’s achievements.

Figure 4. PQM Support to FMHACA and Achievements (2010–2017)

PQM Support	FMHACA Achievements
- Supported the lab to establish and maintain laboratory quality management system (QMS). - Supported development of new quality manuals and SOPs and revision of existing ones. - Supplied equipment, reference standards, chemicals, and reference books. - Supported maintenance and calibration of lab equipment and identified local resource for sustainability.	✓ FMHACA’s main lab – the first government lab in sub-Saharan Africa to be ISO 17025 certified – identified and banned the distribution of nearly 70 million defective condoms. ✓ Shared information about poor-quality condoms with neighboring countries, which took action accordingly.

¹² Reference standards are chemical substances used to determine if a product meets compliance requirements and establish the quality benchmark against which test results are compared (e.g., for purity, content, and stability).

PQM Support	FMHACA Achievements
- Assisted internal and external audit of the lab. - Supported participation of lab staff in proficiency testing. - Supported training of more than 400 staff in QMS and equipment maintenance.	✓ FMHACA budget revised to allow maintenance of its lab, and the National Metrology Institute is assuming equipment calibration. ✓ Four branch FMHACA labs conduct testing of foods and medicines at their level.

Collaboration with stakeholders

Mission staff in Indonesia, Bangladesh, Philippines, Nigeria, and Ethiopia said PQM was very collaborative. Other USAID implementing partners' programs that work with pharmaceuticals or that are dependent on the regular availability of high-quality medicines, including Challenge TB, Global Health Supply Chain Procurement and Supply Management (GHSC-PSM), Systems for Improved Access to Pharmaceuticals and Services (SIAPS), and FHI 360, reported that PQM had been supportive and collaborative, providing important and specialized technical assistance of relevance to public health outcomes they care about.

In Nigeria, the National Pharmaceutical Manufacturers Association reached out to PQM to explore ways in which the program might extend its reach to a broader base of manufacturers beyond the select few to which it was providing direct assistance. It is worth noting, however, that engagement with stakeholders at universities and other academic institutions responsible for developing the new workforce of pharmacists, chemists, and regulators is now included in PQM's more recent strategic framework, which describes its approach to sustainable systems strengthening.

Key informants from global and regional stakeholders based in the field expressed the desire for PQM to be more engaged with them on planning and implementing country activities. (This is also discussed in response to Question 4.) This comes from the perception that duplication of effort in some countries (e.g., Ethiopia) has resulted in wasted resources. Global stakeholders cited PQM's engagement in a WHO-sponsored pilot exercise in Bangladesh¹³ to establish a coalition of interested partners as an example of how they would like to work with the program. In this approach, partners coordinate regulatory strengthening activities by mapping out roles of responsibilities of implementing partners (including PQM) and government agencies.

"It's all about the coalition approach. We should all agree on who does what best. [at the country level]. There are many opportunities for refinement and improvement with how to work better together."

— Global stakeholder

New types of collaborative activities are in the development stage. These can support the increase in manufacturing capacity, especially in Africa, with a focus on increasing regional initiatives. In Ethiopia, the WHO country office called for collaborative actions to strengthen local pharmaceutical production capacity by inviting multiple partners, including the United Nations Industrial Development Organization (UNIDO) and the German Agency for International Cooperation, to contribute technical assistance. PQM is being brought into these discussions; however, the collaboration has yet to be defined.

Producing results against work plans

Twenty of 25 (80 percent) Mission survey respondents reported that PQM was achieving expected results against the work plans. Results are tracked largely as outputs and, to a more limited degree, intermediate outcomes and achievements are reported in quarterly and annual reports. However, three Mission respondents pointed out that, as discussed in response to Evaluation Question 3, until recently PQM did not have a system to regularly track and assess higher-level systems strengthening results that typically accrue over many years and are of increasing interest to Missions. For example, it was noted that the indicator of the number of QC laboratories that have achieved ISO accreditation did not necessarily equate with sustainably strengthened QC laboratories. In fact, some laboratory staff

¹³ <http://www.searo.who.int/bangladesh/cipmeeting/en/>.

interviewed also independently suggested that more useful indicators were needed to demonstrate important lab-related outcomes.

With respect to the timely completion of activities, most (79 percent) Mission survey respondents said PQM timelines were realistic, and only four (16 percent) said PQM did not complete activities as scheduled. Several respondents and PQM staff acknowledged several challenges in meeting timeline deadlines. Until recently, the program did not systematically keep track of how often delays occurred, their duration, or their cause. For example, many of the activities to support manufacturers and labs experienced delays of up to several weeks. According to program staff, delays were sometimes due to the unavailability of PQM experts, but many were beyond the program's control and had to do with the unavailability of experts from other partners or stakeholders, such as the WHO-PQ program. Other delays by counterparts hindered PQM's ability to meet its programmed timelines, such as obtaining official approvals for recruiting staff to conduct training activities.

Evaluation Question 1: Conclusions and recommendations

PQM has been effectively addressing medicines quality issues at the country level by working closely with responsible government agencies and local stakeholders, using increasingly strategic and evidence-based approaches and appropriate technology, and deploying highly qualified consultants. Support to local regulatory authorities to strengthen PQM activities enhanced the PMS functions of NMRAs and helped them take appropriate regulatory actions. In some cases, recalls of poor-quality products affected regulatory decisions in neighboring countries. Overall, PQM clients reported being very satisfied with the quality of technical assistance they received from the program.

As PQM continues to strengthen country regulatory systems and as information about drug quality becomes more widely available, there is a growing recognition that NMRAs will need the help of other sectors to fully execute regulatory actions. For example, in the Greater Mekong Subregion, implementation of PMS helped determine that lack of importation controls and illegal drug markets were the main causes of SF medicines in the market and identified other regulatory system deficits requiring attention. However, the PMS data alone cannot solve problems if regulators, customs officers, police, and commercial entities do not collaborate. In Indonesia, for example, the NMRA is cannot confiscate illegal and SF drugs – that responsibility belongs to importation officials and the National Police. Therefore, more systematic and multisectoral approaches are recommended to support NMRAs to take proper regulatory actions. As a first step, PQM could recommend to the interministerial committee that its activities be assessed for effectiveness and to identify opportunities for improvement.

PQM encountered various challenges working with manufacturers, many of which were beyond its control. The evaluation team recommends that PQM consider conducting a detailed analysis of its unique experiences providing technical assistance to different types of manufacturers (e.g., well-established companies with multiple production lines, new firms with few production lines, and companies that are subsidiaries of others or have subsidiaries) operating in different contexts (e.g., mature or less industrial capacity) and develop guidance for future investments in developing manufacturing capacity. It is likely that the demand for assistance to manufacturers in a variety of contexts will only increase, particularly as African regional pharmaceutical manufacturing development initiatives ramp up. As such, there will be interest in understanding PQM's approaches, including understanding where they should be complemented by other types of assistance to support general business development capacity.

Some noted areas for improvement are PQM's strategic use of advocacy and communication to raise public awareness and to advocate for policy changes and increased support to NMRAs. The program description in the PQM extension document¹⁴ cites examples of PQM successfully using information,

¹⁴ PQM Modification #13, September 23, 2013.

education, and communication techniques, especially public service announcements, in the Asia and Latin American regions to raise public awareness about issues of poor-quality medicines. PQM should consider reviewing these experiences and identify ways to give them new lives, either in different countries or to extend their reach in other ways, and assess how to enhance the sustainability of results.

EVALUATION QUESTION 2

What is the effectiveness of the program's implementation of USAID/Washington-funded directed core health element work?

Overview

Priorities of the program's TB, MNCH, and NTD health elements have focused on addressing supply-side issues of the global shortages of priority quality-assured medicines. Activities to address these priorities fall primarily under IR2, *Supply of quality-assured priority medicines increased*. These activities include identifying and addressing constraints to manufacturing, providing technical and financial assistance to selected manufacturers to produce them, and providing technical assistance to successfully apply for WHO PQ so that the medicines can be available on the global market. In some cases, the goal was to also increase availability in the local market.

For the most part, the medicines in question are well-known essential medicines that, due to various market constraints, have been considered to be of low commercial interest to manufacturers. In other cases, PQM helped to develop product monographs and other compendial documents to support manufacturers to produce more effective generic products, such as chlorhexidine 7 percent gel, zinc/oral rehydration salts (ORS), prothionamide, and terizidone. While PQM focused on addressing the supply of these medicines, USAID health elements worked with other implementing partners and global stakeholders to address critical demand-side issues.

Activities undertaken to support the malaria health element are primarily categorized under IR3, *Utilization of medical product quality information for decision-making increased*, and respond to the priorities of PMI. These activities primarily involved surveillance activities to provide information to PMI about the quality of antimalarial medicines in countries and the potential diversion of PMI-procured products so appropriate follow-up programmatic decisions could be taken. Surveillance activities eventually came to include MNCH and NTD products, and the information obtained was used to support health element programmatic decision-making.

Appropriateness of technical assistance

PQM's technical focus and activities to support the core health element team are appropriate and within the intended scope of programmatic interests. PQM worked directly or indirectly with manufacturers to provide up-to-date and relevant technical assistance to selected manufacturers to encourage them to add to an existing production line or to change a production line for priority medicines. Assistance ranged from development and introduction of needed monographs and related compendial documents to assistance

"PQM has strong talent with deep regulatory knowledge ... [it is one of] the only groups that has an on-par capability with WHO, and the memorandum of understanding with WHO gives recognition of this, and that is important."

— Maternal health team

"PQM does some things very well, very specific technical interventions, like the [ISO] 17025 laboratory certification. ... They have excellent technical people."

— Malaria team

with increasing the supply of active pharmaceutical ingredients (APIs) to support preparations for the achievement of WHO PQ or Stringent Regulatory Authority (SRA) approval.

Despite these successes, health element leads noted that they did not anticipate some of the outcomes. Specifically, both the TB and MNCH teams said they would have liked to have seen greater diversity in the nationalities of manufacturers. Although work plans have specified in which countries or regions they would seek manufacturers with which to work, much of the work ended up being in China, as PQM understandably sought to start where the pharmaceutical industry is already mature. In a similar vein, health element teams also expressed concern that more suppliers for key products (e.g., kanamycin) have not emerged to create more competitive markets. PQM could not be expected to control how many eligible manufacturers there would be or where they would be found, but it could have provided more and more timely information to health element teams as they progressed in their work to help manage health element expectations about these issues.

Quality of technical assistance

Overall, health element teams found PQM's work to be of high quality and the team providing technical assistance to be knowledgeable.

USAID health element teams expressed that they initially had difficulty assessing the quality of PQM's work because they did not fully understand its technical underpinnings, the importance of milestones, the nature of challenges the program might face, and how to track progress. However, some informants said that although they still did not have clarity about

"PQM training is particularly good because the trainers have hands-on experience with the FDA. With receiving an audit it is better than a local person. The answers they provide are closer to what is required by the FDA."

— Indonesian manufacturer

what PQM actually did, they thought the quality of program support was very good because there were clear results. They recognized that with USP as the implementing partner, PQM has had access to not only a team of highly regarded technical experts overseeing and implementing the programs, but also access to hundreds of USP volunteers, including former USFDA inspectors. Manufacturers, regulatory authorities, and global stakeholders also assessed PQM technical assistance to increase the global supply of priority medicines as first-rate, uncompromising, and always meeting international standards.

Strategic approaches

PQM's strategic approach to addressing health elements' priorities to increase the supply of quality-assured medicines has evolved, beginning under its predecessor, the Drug Quality and Information (DQI) program, which was implemented in collaboration with the USAID-funded Point-of-Use Water Disinfection and Zinc Treatment Project (POUZN) project (see box). Specifically, to address the need to introduce new products or formulations, PQM prepared the ground by developing product monographs and appropriate quality testing protocols when none existed. It further refined the system POUZN developed to attract, screen, and select potential "most likely to succeed" candidates. Whenever possible, manufacturers were sought out and selected in health element priority countries where some of the groundwork for demand creation was also being addressed by other partners following POUZN's model.¹⁵ Individually tailored technical assistance plans were then implemented with manufacturers. PQM described this experience in "Building the Capacity of Local Manufacturers to Increase the Supply of Quality-Assured MNCH Essential Medicines," which was recognized as a best practice at the 2017 Acting on the Call Summit in Addis Ababa, Ethiopia. More recently, PQM used the

¹⁵ The POUZN experience in Tanzania involved a champion manufacturer that was actively engaged in demand creation. http://pshi.fhi360.org/pdfs/TANZANIA%20Zinc_%20Final%201-24-11.pdf.

platform of regional regulatory harmonization in the East African Community (EAC) to facilitate dossier submissions for two manufacturers of chlorhexidine gel, zinc sulfate, and ORS for approval and subsequent availability in the region.

Promoting Manufacturing of Zinc

“Just after publication of the WHO/UNICEF Joint Statement on the Clinical Management of Diarrheal Disease (2004), the issue was that ORS and zinc were recommended for the treatment of diarrhea. However, at the time, there was only one manufacturer of oral zinc, so it was not really possible to be promoting the new guidelines. The question was how to support local manufacturers to help address local needs as well as increase the global supply of quality products. USAID paired up the POUZON project with DQI: POUZN was charged with identifying promising manufacturers, and DQI would then provide technical assistance, for example, developing monographs. It was considered a very productive, useful partnership. Now, [with PQM’s continued support] there are many manufacturers, and many countries have manufacturers. Now, the issues are the same, but the drugs/products have changed (e.g., chlorhexidine).”

— Child health element team member

Despite successes, there have been lessons to be learned with this approach to providing support to manufacturers. The screening process could not help anticipate probable drop-outs due to manufacturers’ inability or unwillingness to address unexpected investment to clear CAPA or for quality process improvements. As discussed in response to Evaluation Question I, manufacturers were not always able to complete their requirements according to an agreed-upon timeline. Delays resulted in scheduling difficulties for PQM technical staff and their consultants. Unfortunately, PQM did not document the progress in activities in a way that allows for an assessment of factors affecting manufacturer performance. However, based on interviews with manufacturers and program staff, a significant factor influencing manufacturers’ decisions to continue to work with PQM was their understanding of the true global market potential for the product(s) in question and if they could formulate a viable business case for engagement, something PQM was not able to address for them. While we might assume, therefore, that delays were sometimes probably due to the process that manufacturers had to go through to get to the point where they felt confident and able to continue working with PQM, this was not documented and is a lost learning opportunity.

Manufacturers that were otherwise willing and able to support health element priorities were sometimes constrained by factors outside of their control, namely the lack of quality-assured APIs. To address this issue, PQM adopted a multi-pronged approach that included improving the capacity of API manufacturers by creating a catalog of qualified API suppliers to share with manufacturers. The program also explored more innovative solutions to addressing this challenge at the global level. For example, to support the GDF, PQM drafted a concept note for the creation of an API bank to support the manufacture of finished pharmaceutical products (FPPs) TB products (at the time, capreomycin and kanamycin) at below-market prices. Manufacturers are now compiling their dossiers for submission to WHO PQ. The program also developed an innovative solution to addressing shortages by adapting the contract manufacturing model for manufacturers of cycloserine, capreomycin, and kanamycin, which, with PQM support, also resulted in a negotiated price reduction for the FPPs.

PQM’s PMS activities evolved from a limited, primarily Mission-funded activity to generate evidence to substantiate the need for improvements in country QA systems to become one of its more useful and strategic tools to support core health element programs. The methodology and application became more rigorous with stronger sampling strategies, consistent across countries and over time, and more strategic with more clearly defined options for the use of results (e.g., advocacy campaigns and information-sharing with WHO and other stakeholders).

Despite this success, the health element teams expressed disappointment that PQM has not been more strategic and proactive in using or mining the data they generated. As discussed below, health elements

perceive that there were missed opportunities to further translate findings into meaningful information and to identify new opportunities for interventions.

“PQM had good country teams to help collect data, for example through MQM, on product quality, and the results of these activities were used to inform program decisions. But at the larger, global level, PQM did not do that.”

— Malaria team member

Collaboration with global and regional stakeholders

PQM has collaborated with several global and regional stakeholders to achieve intended results of mutual interest to health element teams. This may be considered a core element of the program’s overall strategic approach. This collaboration was facilitated by longstanding individual and organizational relationships, the mutual recognition of competencies and authority, as well as good communications between USAID health element leads, PQM, and stakeholders.

Arguably, one of the most important stakeholders for the health elements is WHO’s Department of Essential Medicines and Health Products. PQM works in close collaboration and coordination with the WHO PQ program to ensure that manufacturers of priority TB, NTD, and MNCH commodities submit acceptable applications for PQ. Indeed, WHO PQ reported that PQM’s assistance with identifying potential manufacturers significantly helped to expedite the PQ process and allowed its often overstretched staff to focus on pending issues that manufacturers needed to answer or solve. PQM has also been working with WHO PQ by sharing important information about medicines quality discovered through its PMS activities. According to WHO, mutual recognition of technical competence and open communications around joint work planning have been key to these achievements. PQM and WHO have been working to establish a memorandum of understanding regarding how sensitive and confidential information would be managed.

“The relationship with PQM [senior management] has been pretty good, and there is active interaction. The importance of good communications cannot be overstated.”

— WHO informant

Similarly, to support the MNCH team, PQM initially worked with the United Nations Children’s Fund (UNICEF) to share information about supply needs and potential new suppliers for zinc and zinc/ORS, chlorhexidine, and other commodities. Later, at the direction of the MNCH health element teams, the relationship was structured around the framework of the multi-stakeholder technical resources groups that emerged in response to recommendations of the UN Commission for Life-Saving Commodities for Women and Children (UNCoLSC) that work to identify priority issues and develop coordinated work plans. Through this relationship, PQM provided information to manufacturers that might be interested in receiving technical assistance and information about the potential demand for key commodities.

With the TB program, key global stakeholders in activities to increase the supply of important TB products included the WHO PQ program, the GDF, and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). However, though PQM has helped increase the availability of affordable TB products at the global level, these stakeholders suggested that its effectiveness might be enhanced if it could exchange more information about its activities, have a stronger market orientation, and/or identify more regional or networked solutions.¹⁶

As regional initiatives ramp up, PQM (and by extension USAID) has received some criticism from stakeholders regarding the lack of initiative to reach out to global partnerships operating in the same technical space. Examples given included global partnerships coordinated by WHO, such as the Global Steering Committee for Regulatory Harmonization on Quality of Medicines and Supply Chain Management, and an interagency pharmaceutical coordination group hosted by WHO. (These are discussed in more detail under Evaluation Question 4.) As one informant said, reaching out to global

¹⁶ The USAID TB team acknowledges that these suggestions are more appropriately directed to USAID than PQM.

partnerships would “promote collaboration and synergy, as well as overall efficiency.” The MNCH and malaria health element teams are aware of these initiatives and have begun to advocate to increase activities through these initiatives.

Producing results against work plans

As indicated in the extension award document and in more recent program reports, PQM has produced significant results, at times exceeding expectations, in increasing the supply of quality-assured medicines for TB, MNCH, and NTDs. Among these are:

- Twenty TB products, including APIs and FPPs, have obtained WHO PQ or SRA approval.
- UNCoLSC’s goal of having at least three manufacturers per QA commodity by 2015 was reached, with a total of 12 new manufacturers, and PQM continues technical assistance to six new manufacturers of MNCH products.
- WHO PQ or SRA approved four NTDs with PQM’s technical assistance, and the program is engaged in technical assistance with 11 new manufacturers of NTDs.
- PQM has provided important, and in many cases actionable, information about medicines quality that USAID, regulatory authorities, and researchers were able to use to develop interventions.

While PQM core health element results are more straightforward and easier to define than those of country programs, all health element teams interviewed unanimously agreed that it was often difficult to understand PQM’s progress in completing activities. Work plans typically spanned multiple years and changed often, especially with respect to the work with manufacturers. The key indicators that the health elements use to assess progress in work plan implementation are the annual PQM budget (expenditure) burn rate and pipelines, both reported by the program. Activities were broadly described and corresponding budgets were not detailed. A review of work plans against funding profiles revealed long planning and implementation periods combined with sometimes tardy receipts of USAID obligations. In more recent years, the pace of expenditures has increased as activities, especially those with manufacturers, have progressed and results are starting to emerge. The need to improve work plans and communicating results are further addressed in responses to Evaluation Question 3 (regarding deficiencies in PQM’s M&E system), and Evaluation Question 5 (regarding management issues).

Comments from USAID Health Element Team Members

“PQM was slow to deliver. Every year they identified a result of one new manufacturer in their M&E plans. They have many outputs but they are not meeting their goals.”

“I wish there was a way to monitor or benchmark their progress over time so that we can recognize how things are going.”

“There are delays, but to be fair, there are many factors beyond the control of PQM. They are things that have to do with the manufacturers or other entities, and PQM is dependent on them so it impacts their ability to move faster in some cases.”

“They can go a long time without spending down. They have large pipelines. I don’t know sometimes if they are maybe over-budgeting, or is the issue that they are really not able to burn funds because they are held up by [the] pace of manufacturers’ work?”

Meeting requests of health elements

Health element teams reported that PQM has been able to meet their requests with respect to defining an appropriate and relevant scope of activity and collaborating with stakeholders. However, they also noted that the program could have been more proactive and reached out beyond the immediate health element requests. For example, the malaria team reported that PQM missed critical opportunities to

provide PMI with important insights by failing to analyze data they had collected from surveillance activities. Similarly, the child health team did not feel that PQM was providing sufficient perspective or guidance to USAID to identify opportunities to fill gaps in the global agenda with respect to child health products. Furthermore, the

“There has been a tendency for PQM to go for the low-hanging fruit, and USAID has had to remind PQM several times to go after some of the harder drugs, like levofloxacin, instead of moxifloxacin. There are drugs that are facing real shortages, like clofazimine, that did not get enough attention.”

—TB team member

NTD team said it was unfortunate that they learned from the TB team – not PQM directly – about how the program was working with manufacturers, because they had been grappling with supply issues similar to those the TB team was addressing (e.g., the lack of API for praziquantel, then lack of manufacturers and need for market shaping approaches). The expectation was that PQM should have been able to identify the parallels and explore them with the NTD team much sooner, which may have resulted in a timely change in strategy for the team.

Responsiveness in communications with health elements

Health element teams reported that PQM had become more responsive in its communications over time. This included responsiveness and the timely submission of work plans, regular reports, and ad hoc requests for information. According to one team member, there used to be more delays in communications, especially requests for activity status updates, because there was a high level of dependence on the availability of the program director, who was the point person for most of the core health elements: “There was no back-up, for example, when the director was away.” As discussed under Evaluation Question 5, the program’s new management structure allows the deputy director of core and country programs to assume this responsibility and delegate accordingly.

Evaluation Question 2: Conclusions and recommendations

Health element teams and stakeholders readily point to numerous significant program achievements over the years, and they report confidence in the quality of PQM’s technical assistance. However, they also reported that they sometimes struggled to understand the program approach and details of PQM’s technical activities, the relationship of these activities to one other, and even the rationale behind them. Opportunities to further enhance or better communicate the effectiveness of core health funded activities include the following:

1. The lack of an explicit strategy detailing the procedures for dealing with situations in which progress stalls contributed to the mystification of PQM’s highly technical work. This has been particularly true with respect to the support provided to manufacturers, as discussed in the response to Evaluation Question 1. The elaboration of an explicit strategy – one based on program experiences and including documentation of all steps taken and issues encountered – will increase transparency and confidence in PQM’s progress toward achieving intended outcomes.
2. Although USAID and stakeholders reported being satisfied with PQM’s work, they also identified ways in which they felt the program could have a greater impact on increasing the availability of quality assured medicines and combatting SF medicines. Specifically, USAID expressed frustration that PQM was not more proactive about analyzing and using data that was at its disposal and identifying new opportunities or emerging issues, rather than simply reporting on a completed task or requirement. Program staff should gain awareness of and confidence in their role in supporting USAID in these ways.
3. A key element of success with health element-funded work was PQM’s vast experience operating at the global level with other important development partners, including WHO, UNICEF, GFATM, and GDF. USP’s close association with USFDA also lent credibility to the

program's technical assistance to manufacturers. However, as new partnerships with non-traditional partners evolve to work on regional issues of access to quality-assured medicines, PQM has a new opportunity to share experiences and lessons, and continue to build on work with regional initiatives (an approach it has already taken to support increasing the supply of MNCH commodities in the EAC).

EVALUATION QUESTION 3

What is PQM's ability to demonstrate that their work has contributed to the sustainable strengthening of medicines QA systems?

The previous sections provided several examples of how PQM's technical assistance contributed to the strengthening of QA systems, including addressing concerns of sustainability. However, the objective assessment of the effectiveness of PQM activities in systems strengthening and sustainability was a challenge because there was not a fully developed results framework with a corresponding measurement system to support the demonstration of the achievement of the results. From an implementation science perspective, the lack of evidence structured around such a framework and measurement system impairs the ability of PQM – and others – to assess and learn from its work and assure reliable attribution. This section reviews PQM's strategies and tools to support program management for the demonstration of the achievement of stated goals and objectives, including recent efforts to address current deficiencies.

"It looked like the program was 'building a ship as it sailed,' meaning they simply did not have or did not communicate an overarching guiding plan or vision to tell the story of what they were accomplishing. For example, what does it mean that 40 standard operating procedures are developed?"

— AOR team member

"PQM [is] not good at conveying their successes, which makes it hard to understand, concretely, what they accomplish, or even exactly how."

— MNCH team member

Results framework and pathway of change

A results framework is an important component of a program strategy in order to achieve the overall strategic objective/goal. The program was initially designed within a framework comprising four intermediate objectives (referred to as "strategic approaches" at the time; see Table 6) that were underpinned by supporting IRs. PQM and USAID used this framework to define approaches and organize activities up through the extension.

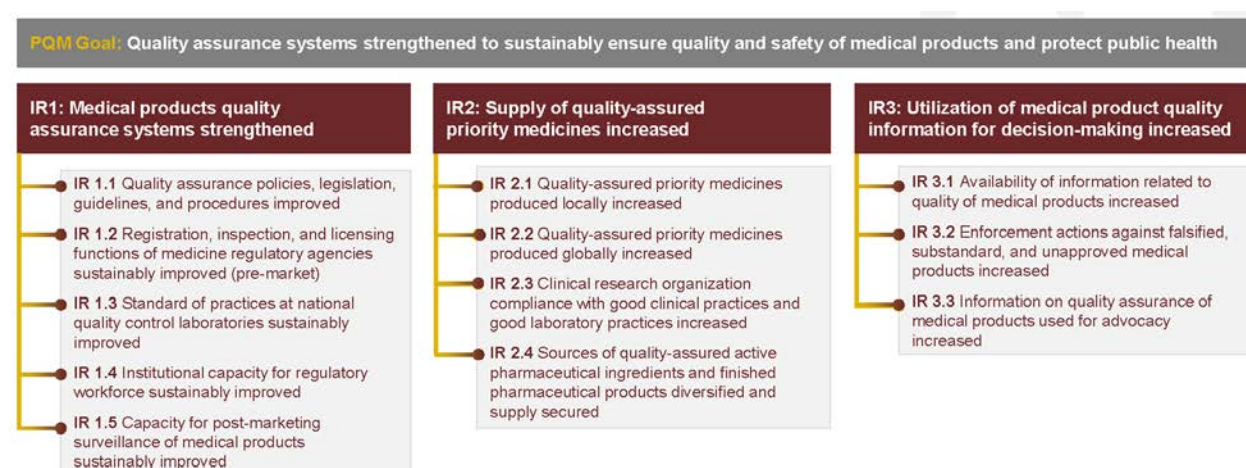
Table 6. PQM Results Framework, 2009–2016

Overall Objective: To Ensure the Quality, Safety, and Efficacy of Medicines of Relevance to USAID Health Programs	
Intermediate Objectives	Intermediate Results
1. To strengthen national QA systems	1. More developing countries have a better functioning/fully operational medicines QA system in place
2. To increase the supply of good-quality medicines of direct relevance to priority USAID health programs	2. Increased availability of good-quality medicines of direct relevance to priority USAID health programs
3. To combat the availability of SF medicines	3. Reduced presence of substandard and counterfeit medicines in the supply chain of developing countries

Intermediate Objectives	Intermediate Results
4. To provide technical leadership and global advocacy regarding the importance of medicines QA	4. Improved medicines QA tools and mechanisms, increased awareness of their importance, and increased funding for their implementation and use

In 2016, PQM revised the results framework to better reflect a more targeted goal of sustainable systems strengthening. The program’s updated goal became “quality assurance systems strengthened to sustainably ensure quality and safety of medical products and protect public health.” The three IRs were updated to *Medical products quality assurance systems strengthened* (IR1); *Supply of quality-assured priority medicines increased* (IR2); and *Utilization of medical product quality information for decision-making increased* (IR3). These include 12 sub-IRs (Figure 5).

Figure 5. PQM’s Results Framework, 2016–2019



A complete results framework generally includes an exposition of the thinking behind selected interventions, including the mode of implementation, expressed as a development hypothesis or pathway of change.¹⁷ Unfortunately, there is no indication that PQM has developed this component of its framework, which would have helped it to communicate achieving IRs and approaches.

Although PQM was not required to provide an explicit pathway of change or a theory of change, the latter a requirement for newer USAID programs, the extension document summarizes the program’s past performance and includes the rationale behind strategic approaches in ways that approximate a pathway for change.

A review of PQM documents, such as work plans and case studies, suggests that there was a progression of refinement regarding the thinking around program technical approaches and strategies. For example, more recent program documents do refer to employing “systems-based thinking” and “sustainable solutions,” but there is no clear definition or application of “systems thinking.” There is a brief mention on page 6 of the modification agreement of what PQM considers the three areas of its own “systems-based approach,” but it does not provide any definition of a “systems approach” in health systems strengthening beyond its own. (Despite varying definitions, the commonality is the “building blocks” that make up health systems.) Moreover, there is no attempt to demonstrate the ways in which PQM’s “systems approach” contributes to QA systems strengthening and, by extension, greater health systems strengthening. The fact that PQM did not make a clear linkage between its systems approach and how it contributes to strengthening the entire health system is unto itself a demonstration of the

¹⁷ https://www.measureevaluation.org/prh/rh_indicators/overview/results-framework.html

program not grasping the fundamentals of a systems approach. Although PQM has developed a definition of “sustainability” and has started to address some financial and human resources constraints to sustainability in Kenya, Ethiopia, and Peru, this is an incipient effort and not yet been mainstreamed. These deficiencies have limited PQM’s ability to demonstrate its value-add as **one** actor working to strengthen the larger health system.

M&E plan

The original PQM strategic objective framework was not used to support the development of an M&E plan; instead, it was used as a tool to categorize activities and indicators and was limited to outputs. For example, outputs included the number of people trained, number of documents published, and number of medicines tested. Since the extension and the development of its new results framework, PQM has been undertaking the formidable challenge of developing new indicators to be used for new work plans while trying to “retrofit” old work plans and activities to the new framework. It adopted Newdea, an online program management tool, to help track the new indicators in the new framework. At the time of data collection, PQM had input for approximately 80 percent of all prior work plan information, including indicator data.¹⁸

PQM’s M&E framework and corresponding tools were not fully implemented at the time of data collection for this evaluation. Based on a review of the existing documentation and interviews with program staff, it is clear that the framework is intended to be used to monitor output- and outcome-level indicators (some indicators labeled “outcome” are actually “output”) and to gauge the effectiveness of program activities and technical approaches. There are two types of indicators, both developed through a participatory and consultative process with PQM staff: shared, program-wide indicators (“Level 1 indicators”) and country-level indicators (“Level 2 indicators”) that capture country-specific progress. Most of the indicators track outputs and, as stated previously, there is no direct causal relationship established between activities, outputs, and outcomes. Although there are some logical connections between activities and outcomes (e.g., FMHACA achievements in Ethiopia, discussed under Evaluation Question 1), PQM does not measure attribution by acknowledging other stakeholder activities or external factors that may facilitate or hinder its work.

Evaluation Question 3: Conclusions and recommendations

PQM’s ability to demonstrate its contribution to the larger goal of strengthening medicines QA systems is largely limited to a series of case studies that lack sufficient clarity and rigor in demonstrating the effectiveness of program activities and processes. One of the challenges that PQM faces in this regard is that many outcomes of its work are not linear or always obvious. A central tenet of how systems operate is that a change in one part can affect another (known as the “butterfly effect”). This effect can be intentional or unintentional, negative or positive. For example, increased detection of substandard medicines may lead to confiscation efforts, thereby requiring more budgetary spending that may detract money from other health initiatives. In effect, the outcomes of PQM’s work may not be evident in the realm of QA systems strengthening but the impact may be reflected elsewhere in the system, and vice versa. This is not an issue unique to PQM – it is a common to all health system interventions. PQM can measure how its work contributes to systems strengthening only with an in-depth understanding of how systems behave (complex system theory) and how the health systems in which it works function.

For PQM (and other programs) to scale up or replicate its approaches to other contexts, it is essential to have clear descriptions of the ways in which activities are implemented and how activities and corresponding processes lead to outputs and outcomes. Just as important is information about the system itself that affects PQM’s work (e.g., its inherent flaws and risks, facilitators of change). Given the its size, the recognized importance of its work, and its growing visibility, PQM needs to consider how it can better demonstrate its value and “tell its story.” For example, it will need to think beyond the typical

¹⁸ PQM reported having completed entry of information from all prior workplans by March 2018.

“input – black box – output” paradigm¹⁹ in order to identify and operationalize the most relevant and valid outcome measures for the program.

The evaluation team encourages PQM to consider how outcomes can be described as components of the larger health system, and as having effects on issues of system feedback loops, governance, stewardship, financing, processes and flows of information, and stakeholder behavior. Identifying the potential positive and negative effects of its work on the whole system, as well as limitations of its effects, will help PQM attain a fuller understanding of the value of its work as contributing to the strengthening of the larger health system. It will also provide essential information for scale-up, replication, and sustainability. This exercise may be included as part of the work plan development process as it relates to the results framework and theory of change, and may also be useful for USAID by revealing opportunities for the collaborative engagement of other Agency partners or entities as part of the larger systems strengthening agenda.

The evaluation team also encourages PQM to continue developing the systems thinking and approach underpinning its results framework. The WHO offers a robust and widely accepted systems thinking approach that may help PQM align its activities and approaches (including justification) with other systems strengthening interventions. Once this framework has been adapted to the results framework, a pathway of change can be developed. Annex IV provides useful tools to help with developing a theory of change or pathway of change.

Last, the WHO systems thinking approach, based on its “Framework for Action,”²⁰ which identifies six “building blocks” that make up health systems, offers PQM an appropriate framework to build its interventions upon and around. This framework will help PQM build on the work of other health systems strengthening efforts, identify inherent risks within a health system, understand how its work interacts with the other building blocks of the health system, and make clear its added value to strengthening global QA systems.

EVALUATION QUESTION 4

How well is PQM advancing the medicines QA agenda and providing global technical leadership in medicines QA?

USAID Global Health programs provide many medicines to LMICs each year; ensuring these medicines are of high quality is PQM’s overarching goal. In the 2013–2019 extension and ceiling increase, USAID and PQM refined and developed intermediate objectives that would help achieve this goal. A new IO was added, IO4, *Provide technical leadership and global advocacy regarding the importance of medicines quality assurance*. This section outlines PQM progress toward this IO. The program’s anticipated approaches and activities under this IO for 2013–2019 are robust and include the following:

- Continue to provide a platform for global advocacy and technical leadership in medicines QA on behalf of USAID.
- Provide critical analysis and input, and represent USAID on domestic, international, and global technical committees for advancing internationally recognized quality standards to address SF medicines.

¹⁹ Ludwig von Bertalanffy, one of the founders of General Systems Theory, argued that the prevailing paradigm for scientific inquiry based on the Newtonian concept of closed systems and linear analysis did not consider a subject’s surroundings, thereby creating a “black box” that obscures the true nature of cause and effect. Ludwig Von Bertalanffy. *Perspectives on General System Theory: Scientific-Philosophical Studies* (1976).

²⁰ World Health Organization. [Everybody’s Business: Strengthening Health Systems to Improve Health Outcomes: WHO’s Framework for Action](#). Geneva, WHO (2007). The six building blocks are service delivery; health workforce; information; medical products, vaccines, and technologies; financing; and leadership and governance (stewardship).

- Harness its own networks and leverage USP's significant resources for relationship building, leading to a successful implementation of actions to achieve the stated objective. Partnerships, initiatives, and relationships specifically mentioned include WHO; the Institute of Medicine; the Advisory Group of the Stop TB Partnership; Saving Lives at Birth; the Grand Challenges Initiative; the Worldwide Antimalarial Resistance Network; the Technical Working Groups on the African Medicines Regulatory Harmonization; UNIDO; and the Pharmaceutical Manufacturing Plan for Africa.
- Advance the methodology, field-testing, and deployment of innovative tools appropriate for resource-limited countries in partnership with Boston University. Support promising tools such as Minilab™ and PharmaChk™ toward full deployment.
- Promote country ownership and financial sustainability by developing guidance documents, references, and advocacy tools for NMRAs and government leaders.

PQM's accomplishments prior to the 2013 extension are fully documented in USAID's "Response to Questions for Extension and Ceiling Increase of the Promoting Quality of Medicines Program" of August 26, 2013. As such, the evaluation team focused on PQM's performance after the extension.

Global technical leadership

Since its inception, PQM has been a champion for the role medicines QA plays as part of USAID's larger effort to ensure the quality and safety of medicines. To this end, PQM has made presentations at numerous national and international meetings and conferences, as well as through local media outlets, to present data obtained from its activities and to draw attention to the need for quality-assured medicines. More recently, it has become more actively engaged with global stakeholders (e.g., WHO, UNICEF, GFATM, and the GDF) in activities to further the agenda of increasing the supply of priority public health commodities. PQM has also become increasingly engaged with regional entities, especially the EAC through the African Medicines Regulatory Harmonization initiative, through joint planning and training activities covering issues of common concern.

Despite this engagement in technical activities, some global and regional stakeholders said PQM was not sufficiently visible at global and regional conferences and meetings. Some respondents also felt that PQM was not present at important high-level meetings (or, that when it was, it was mid-level staff) and has not successfully managed their expectations regarding their roles. In addition, it is not evident to some stakeholders that PQM does not have policymaking authority, although it represents USAID interests in those meetings. For example, in November 2017 the 3rd Biennial Scientific Conference was held in Accra. Organized by the New Partnerships for Africa's Development Agency and the International Federation of Pharmaceutical Manufacturers & Associations, in collaboration with renowned global health partnership organizations, its theme was "Sustaining the Momentum for Regulatory Harmonization in Africa" — a subject that is fully aligned with the quality of medicines mission of USAID and PQM. Some respondents felt that either USAID or PQM leadership, or both, should have been at the conference. Instead, PQM was represented by technical staff who were unable to contribute to deliberations.

"We would like to have a stronger USAID presence at meetings with other partners, of someone with some weight or authority, to be able to discuss things like priorities and collaboration."

— WHO representative

Most national, regional, and global stakeholders who work with PQM are aware that USP is an autonomous organization. However, a number of stakeholders are unable to discern between PQM and USP, USP and USAID, or between PQM and USAID. As one WHO informant said, "It has been a little confusing at times to know which side of the house you are talking to, whether PQM or USP."

Information dissemination

With relatively little cross-bureau funding, PQM has produced several peer-reviewed publications in which it shared its experiences. It is noteworthy that PQM has published research on the prevalence of SF medicines and made presentations at high-profile venues advocating combating SF medicines. It has promoted program monographs, compendia, and guidance documents (e.g., prescribing and use guidance from a public health perspective) through media releases. The recently updated PQM website (www.usp-pqm.org) provides access to program reports, journal articles, and fact sheets, but does not provide links to related initiatives similar to PQM or global stakeholders. Some stakeholders and partners mentioned that PQM had a passive and non-strategic approach to information dissemination. For example, one partner suggested that PQM should produce and share information within the context of implementation science (e.g., process evaluations, generating evidence for immediate application).

Advocacy and public awareness-raising

PQM does not appear to have a targeted and strategic approach to advocacy on issues of QA of medicines in resources-constrained settings. Although PQM supported the development of some public service announcements about SF medicines and a related public awareness video has been released, the video was produced in English. The evaluation team was perplexed that there were no other translations, such as French or regional languages. The program website, under the tab “PQM in the News,” lists 26 articles that aim to raise public awareness about issues of poor-quality medicines in LMICs, but less than half were published in local newspapers in areas where PQM works (most were from Nigeria). Limited success on advocacy has been mentioned in previous sections, in the response to Evaluation Question 1, for example.

QA tools and approaches

PQM has been notably successful with the development and deployment of several QA tools and approaches. Some tools are now reaching the full deployment stage, while others are still in development. PQM has developed guidance documents and tools for public use, including pharmacopeia monographs and compendial tests, and testing methods supported by accessible existing technological platforms such as Minilab, and the Three-Level Approach to address QA throughout supply chains.

The program has leveraged its experience working in resources-constrained countries to support the development of appropriate, reliable, and affordable technologies for the detection of SF medicines. For example, the proof of concept for PharmaChk, a cost-effective tool that can detect substandard medicines using innovative microfluidics technology, was made possible through a synergistic partnership with Boston University. PQM is exploring similar relationships with other technology and research institutions for related emerging initiatives.

PQM has contributed tools and approaches of significant importance to global and regional stakeholders. These include NMRA Gap Analysis and GMP Roadmap construction tools, and the Poor Quality Medicines ALERT which, together with information collected in USP’s Medicines Quality Data Base (MQDB), are contributing to a new WHO PMS database. Other PQM emerging tools and approaches include the framework for implementing a risk-based PMS system, CLM, and national and cross-national technical capacity building. In addition, PQM was able to leverage USP’s Center for Pharmaceutical Advancement and Training (CePAT) in Ghana to expand the reach to global stakeholders, further reinforcing program efforts. An example of the transition of a PQM initiative to a regionally owned initiative is the Network of Medicines Quality Control Laboratories – Sub-Saharan Africa to the African Medicines Quality Forum.

Approaches to regulatory systems strengthening

PQM’s technical assistance for regulatory systems strengthening has appropriately focused on the individual country level, with interventions tailored to the local issues. Over time and with more experiences, PQM’s overall approach has become more deliberate and strategic and, as discussed in

response to Evaluation Question 1, there are numerous examples of in-country successes. The further development the program results framework for regulatory systems strengthening based on these experiences, discussed in response to Evaluation Question 3, together with the full complement of tools and methodologies, will be a tremendous contribution to the field. Indeed, the rapidly emerging and increasingly salient role of the African regional initiatives in furthering the agenda for regulatory systems strengthening points to the importance of having more unified approaches among all global and regional partners, and the urgency of having PQM's experiences more broadly disseminated and understood sooner rather than later.

As discussed in response to Evaluation Question 2, USAID health element teams have begun to perceive the value of aligning with regional initiatives, especially those in Eastern and Western Africa, as a way to expedite achievement of health element goals. What this means for PQM in programmatic terms, however, will need to be made very clear to all stakeholders. For example, PQM's bilateral, country-by-country direct partnership approach to providing technical assistance for regulatory systems strengthening is currently perceived by these regional initiatives as contrary to or not sufficiently aligned with their own multi-country, regional approach. This perception, however, appears misplaced because support for regional regulatory harmonization is likely to still require direct technical assistance for at least some countries, even if within a regional framework.

As regional initiatives to support medicines regulatory systems continue to gain momentum, some partners and stakeholders are seeking to "find" their appropriate niche in those efforts. It is critically important that PQM be able to communicate to all stakeholders what contributions it can make to these efforts and to be transparent in sharing how it works with other partners in-country and for what purpose. For example, a WHO stakeholder said they were initially unaware of, or in disagreement with, PQM's selection criteria for manufacturers to be supported, demonstrating a lack of understanding of the purposes of PQM engagement with manufacturers (i.e., support for health element immediate supply goals versus broader regulatory system and manufacturing sector strengthening goals). This stakeholder also expressed concern about the lack of transparency with respect to the structure for engagement with the manufacturers and the lack of engagement modalities to work with other layers on ground. These misunderstandings remained unaddressed for some time. More recently, however, according to WHO, there are reports that communications and mutual understanding with PQM have improved.

Evaluation Question 4: Conclusions and recommendations

Many important PQM contributions are evident in the advancement of medicines QA. These contributions will become even more evident as the program documents these experiences to correspond with a refined results framework for QA systems strengthening, together with supporting tools and methods. However, a more effective and targeted strategy is needed to communicate these contributions more broadly.

Although stakeholders recognize PQM's global technical leadership role, there is a marked lack of clarity among stakeholders about how this role might be carried out, especially in the context of the increasing importance of African initiatives to strengthen regulatory systems. Some national, regional, and global stakeholders identify PQM as an autonomous organization, and quite a number are unable to discern between PQM and USP, USP and USAID, or PQM and USAID. Similarly, although there are examples of how PQM has engaged with global and regional partnerships and initiatives, its visibility is low, which also means that USAID's presence is perceived to be minimal. USAID should consider what role it would like to play within this context and determine the appropriate form of engagement.

As their roles and inter-relationships are largely unclear to stakeholders, USAID, USP, and PQM should develop a mutual understanding of how to address their appropriate representation at venues for technical or policy matters of regional and global dimensions. These issues can be addressed through a

communications plan. The current plan needs to be further developed and implementation started. This is discussed in the response to Evaluation Question 5.

EVALUATION QUESTION 5

How have PQM's management structure, processes, and staffing patterns helped or hindered progress toward achieving the program's goal and results?

Since the beginning of the program in 2009, PQM's management structure, processes, and staffing patterns have undergone significant changes. Initially, the management structure was essentially identical to its much smaller predecessor program, DQI. However, the rapid increase in the level of funding and complexity of programming needs that accompanied the program extension highlighted the need to reconsider how PQM had been managed. Concerns included the need to be more accountable and transparent with budgeting and expenditures, the lack of rigorous M&E, and the need for a revised results framework in light of the emphasis on sustainable systems strengthening. There was also pressure from some Missions to establish country offices to improve program efficiency and responsiveness in communication with counterparts. These issues are discussed in this section.

Management structure

PQM adopted the management structure of its predecessor, the much smaller DQI program. The PQM management structure was fairly simple and appropriate for the size of the program. It included a director who reported directly to the USP's Division of Global Health Programs (GHP) and served as the face of PQM on all key global technical leadership and advocacy activities. The director was supported by one deputy who provided general technical oversight and management support to program managers. Program managers and other technical support staff were recruited primarily from existing USP technical staff. Staffing aimed to match portfolio technical needs with staff technical qualifications (including language skills). The program did not have any fully dedicated M&E staff, and operations, finance, and support for compliance with U.S. Government rules and regulations came from other USP corporate offices.

The structure that emerged in response to the program extension request is in Annex V. However, perhaps the most significant changes to the program management structure occurred outside of the PQM program structure in USP's GHP. USP made significant investments in developing its operations team and partnerships and learning team (where M&E is housed). New positions were created to develop these corporate functions, primarily for the purpose of supporting PQM and ensuring consistent implementation of program management processes, standards, and policies, including in the field.

PQM's new management structure includes a second deputy to directly manage the technical teams supporting the technical areas of manufacturing, laboratory strengthening, and regulatory systems strengthening, as well as capacity development and intrinsic design. These headquarters (HQ)-based teams are responsible for developing strategies and approaches within the technical areas and providing direct technical support to country programs. The deputy for core and country programs provides direct oversight and guidance to HQ-based program managers working on core health element and country programs. Country program managers are responsible for all country program-specific geographic regions (Africa, Asia, and Eastern Europe, and Central Asia), and the chiefs of parties in the field (Ethiopia, Indonesia, and Nigeria, with offices being established in Pakistan and Bangladesh at the time of this evaluation) report to them. The PQM organizational chart also now includes non-technical program coordinators who support operations and M&E.

Although these changes did not occur quickly and, understandably, created challenges, the AOR team reported observing improvements in program management. In particular, the AOR team feels that it is only because of these changes within GHP that PQM could open field offices as quickly as it did.

Processes

PQM has adopted a cross-functional (i.e., “matrix”) management approach in which the technical focus area lead is responsible for ensuring that all core and country program managers use the appropriate tools and approaches to that functional area, and that program coordinators do the same for operations and finance and M&E. (See Annex V.) According to PQM staff, this reduced the possibility of technical staff trying to implement their own untested approaches and created more transparency around how activities were planned and budgeted and how outcomes were measured and monitored.

Several key tools and processes have been revised or newly developed to support the new management structure. These include new activity-based work plan budget templates, budgeting and expenditure tracking tools, and corresponding SOPs. USP also started to use a web-based program management tool, Newdea, to support real-time coordination between HQ and field office staff. HQ and field-based staff who were interviewed for this evaluation expressed appreciation for many aspects of these new tools, especially those related to finance and operations. They reported that the tools have helped with the development of more transparent and realistic budgets²¹. PQM program managers and chiefs of parties also report that expenditures can be tracked more reliably, making that information more useful for monthly program monitoring and decision-making.

A review of work plans from the outset of the program revealed that the plans had become more comprehensive and consistently organized. The content is now more harmonized across all portfolios and has a greater focus on sustainability and systems strengthening concerns.

The process for developing annual work plans prior to 2015 required lead technical staff to work with Missions or health element teams to determine the scope of the activity, based on a proposed budget from USAID. PQM staff would then refine the scope and develop corresponding budgets and schedules. Once a year, all HQ and field staff convened at HQ offices with the AOR team to present their achievements, discuss draft work plans, and share ideas and experiences. However, PQM did not have any formal guidance for staff on how to develop or review work plans, including how to develop budgets. After 2015, under new leadership, PQM critically assessed this process, gave it more structure, formalizing the steps through documented guidance, and incorporated the new M&E system and budgeting procedures. All work plans are now submitted in a timely fashion for AOR approval.

To ensure that the core and corporate programs do not become siloed and will benefit from inputs from a variety of in-house technical experts, the work plan process involves a series of all-staff consultative meetings and presentations at HQ. PQM field offices appreciate that they can drive the development of their work plans but are also vetted along with all HQ-based programs. In addition to being shared at annual meetings, work plans are available to all staff through the Newdea platform. This new process has helped ensure that all staff are aligned on the direction and progress of the program, which was a concern before this process was implemented.

Although PQM staff generally appreciate the work plan development process, some feel that the work plans themselves are too cumbersome. From the perspective of USAID health element teams and Mission activity managers, the work plans often contain extraneous information and do not focus

“The work plans now have a stronger systems flavor, which is understandable. But this is at the loss of [health element] specific issues.”

— USAID health element team member

“The work plan development process is OK but the details need to be worked out more, with the team. There are many generalities. It needs to be more [health element] specific.”

— USAID health element team member

²¹ Twenty of the 25 (80 percent) respondents to the Mission survey said PQM budgets were realistic.

enough on their specific concerns. In addition, one third of the Mission survey respondents indicated that the work plans lacked specificity and clarity on how progress is to be monitored.

At the request of USAID, PQM developed a Knowledge Management (KM) and Communication Strategy (July 2017–September 2019). This strategy is not yet fully developed and is lacking many key components, including how communications will be managed within the program and with external stakeholders and USAID (e.g., the AOR team, health elements, and Missions). The current USP GHP Communications Plan is not adequate to address PQM's communications needs. For example, it targets only English-speaking external audiences and was not intended to be used to support PQM technical or management needs.

Staffing patterns and human resource management

There are approximately 80 program staff who provide at least 50 percent level of effort. About half of these are locally hired and based in the field. In 2009, all staff were based at HQ.

PQM has been able address its field office technical staffing needs by hiring local talent in the field whenever possible. In this way, it decreases expatriate costs and minimizes the challenges related to language and cultural differences. PQM also considers hiring local staff as an investment in more sustainable solutions, including through south-to-south technical assistance. To retain and further develop field staff, PQM has begun to engage local technical staff to support activities in other countries. For example, Nigerian and Ethiopian staff have provided technical assistance to the Mozambique program.

Although there has been some staff turnover at HQ, including hiring of a new director in 2015, several senior program managers worked on PQM predecessor programs and point to a high level of stability at this management level. Indeed, 13 of the 19 mission survey respondents that are currently working with PQM reported that staff support and human resources management from HQ appears to be “good” or “very good.”

Health element teams, however, reported that HQ has not been responsive enough in increasing their staff to keep pace with the demands. As one MNCH health element team member pointed out, “PQM is supporting 15 products, simply too much for a small team of two or three [staff].” Health element teams opined that activity implementation might benefit from the hiring of public health generalists and program managers to support senior technical staff. Although specific examples were not provided, the inference was that PQM might be more efficient if generalists could be engaged to help specialists carry out tasks that did not require their skills, including communicating about activity progress. PQM identified such an opportunity when the core programs manager position was created in 2015, allowing the TB and NTD technical leads to focus on technical delivery. A model for this approach also exists in the management structure of the Indonesia program, where the chief of party is a public health generalist supported by a team of technical experts.

Evaluation Question 5: Conclusions and recommendations

The new PQM management structure and staffing patterns appear to be appropriate for the size and complexity of the program. USP investments in improving and strengthening program management functions and establishing program offices have had a positive impact on PQM's ability to perform effectively and efficiently. The following recommendations aim to encourage the continued trajectory of improvements.

- I. It is unfortunate that the development of the KM and Communications Strategy has not progressed more quickly. With less than two years remaining, PQM should prioritize the full implementation of the M&E strategy, especially as it relates to the results framework. This experience can be useful to USAID, stakeholders, and other partners as they, too, strive to develop their results frameworks.

2. In consultation with USAID, PQM should reconsider narrowing the scope of its KM strategy. A comprehensive KM strategy and plan builds on a platform of information management that draws from an M&E system, among other sources. The remaining program performance period is likely to be too short to fully develop and effectively implement a comprehensive KM strategy and plan. A more fruitful investment would be to complete the deployment of the Newdea system for program management and M&E, focusing on the information management element of the KM plan to optimally support a more comprehensive communications strategy.
3. If PQM intends to include a communications strategy as part of its KM Plan and Communications Strategy, then this information should be included. Otherwise, the title should be changed to accurately reflect the contents. A communications strategy should clearly and comprehensively define target audiences (e.g., USAID, stakeholders from other donor and multi-lateral organizations, and in-county counterparts), corresponding communication needs, and appropriate channels for that communication. Staff roles and responsibilities in the implementation of the strategy should also be included.
4. As PQM further develops interventions and approaches to address issues of sustainability and potential scale-up, it should continue to reconsider what may be the optimal technical and management staffing mix for the program in general and for specific portfolios, both in the field and at HQ. In addition to type of activity (i.e., technical or management), a formal review should also include work flow analysis to identify potential and avoidable bottlenecks affecting important functions, including effective communications.

V. CONCLUSIONS AND RECOMMENDATIONS

The evaluation team identified numerous examples of how PQM has been effective in addressing medicines quality issues. Since 2009, achievement of important outcomes can be tracked as interventions built upon the successes of previous interventions, leading to increasingly impressive results. Over the years, PQM has worked closely with government agencies and local stakeholders to identify best strategies to address the weaknesses in their QA systems, promote appropriate technologies, and build the capacity of QC laboratories, regulatory agencies, and manufacturers. PQM has also successfully engaged with key global and regional stakeholders and made valuable contributions to medicines QA systems strengthening through global technical leadership. The consistent and increasing level of funding from health elements and Missions is a testament to the continued value of the program to USAID.

PQM's work in regulatory systems, national medical QC laboratories, and manufacturing has been, and continues to be, of great import to all stakeholders. There is a general agreement that meaningful improvements in QA of medicines can be achieved if these three areas are addressed, and acknowledgement that what approaches to take, how interventions are designed, and who should be involved will vary based on the specific context. Most country programs are engaged to some degree in each technical area. PQM has made several significant contributions in each technical area, including the development of new and LMICs context-appropriate technologies, management and research tools, and approaches to solving the complex challenges that characterize the landscape of medicines QA.

Manufacturers, regulatory authorities, and global stakeholders alike assessed the quality of PQM technical assistance as first-rate, uncompromising, and always meeting international standards, even as the program faced several challenges as it grew in size and complexity. PQM appropriately responded to management challenges by adjusting the management structure to provide more support to both technical teams and Mission portfolios. It has also been working to strengthen essential program management processes in the areas of operations, finance, M&E, and KM so that it might better track key expectations listed in its ceiling extension document.

In the absence of a clear guiding results framework supported by an explicit theory of change, it appears that early PQM accomplishments in QA systems strengthening were not the result of forward thinking. However, PQM has become increasingly deliberate and strategic in pursuing the results defined as systems strengthening and sustainability and specified in its results framework. This is evidenced in the transition from MQM to risk-based PMS and the application of CLM for capacity building and other evidence-based approaches. The evaluation team is optimistic that as PQM continues to be self-critical, it will continue on this positive trajectory.

PQM's difficulty in demonstrating effectiveness and "telling its story" is perhaps not unique and would be a challenge for all programs working on complex systems issues. It is, however, a significant area for improvement, especially as it affects relationships with key stakeholders and partners. Although PQM was not required to develop an explicit theory of change to accompany its results framework, there is now a demonstrated need to further refine and elaborate on it, including development of a corresponding narrative that provides a clear rationale for how activities are selected, why they are designed as they are, and any issues affecting implementation. Indeed, more recent program publications do include detailed guidelines and extensive documentation of activities, such as the *Guidance for Implementing Risk-Based Post-Marketing Quality Surveillance in Low- and Middle-Income Countries* (2017) and the forthcoming *Strengthening Quality Assurance and Regulatory Systems for Medical Products in Low- and*

Middle-Income Countries (expected in 2018). From an implementation science perspective, a more explicit understanding of the ways in which PQM interventions are intended to function within — and affect — the greater health system is required to develop a measurement system to rigorously and objectively track program outcomes.

Below is the evaluation team’s list of prioritized recommendations for PQM, all of which can be accomplished within the relatively short remaining performance period. Following the list of PQM recommendations are suggested recommendations for USAID.

RECOMMENDATIONS FOR PQM

Strengthen all aspects of communications

Some of PQM’s successes have not been well communicated or documented in a way that can be used to advocate for continued support for strengthening medicines regulatory systems. Familiarizing stakeholders through active communication about PQM, its Mission and operations, including successes and challenges, is urgently needed, as is advocacy for partnerships support to maximize PQM’s productivity and Mission sustainability. USAID, national government, civil society, bilateral aid, and philanthropic and private sectors are all among the groups indicated for targeted advocacy and communication work.

A more comprehensive PQM communications strategy is urgently needed. The strategy should define who should be given specific information, for what purpose, when that information should be delivered, and through what communication channels. The strategy should cover both internal and external clients and promote the active exchange of information.

Further develop results framework and corresponding pathway of change

USAID health element teams and global stakeholders have struggled to understand exactly “what PQM does.” Non-technical audiences and those unfamiliar with PQM’s portfolio struggle to understand how PQM achieves their results. The lack of transparency regarding the processes and pathways of change leads to a “mystification” of PQM’s highly technical work. Adopting a Pathway of Change or Theory of Change as a means to make clear the processes that lead to results, including critical information on mediating variables that impact outcomes, would greatly aid PQM in demonstrating its value-added. With an overarching pathway of change to guide the program, sub-pathways can be developed to support activities *within* and *between* each technical focus area (i.e., regulatory systems, NDQCLs, and manufacturers).

The current PQM M&E system was launched only within the year, and the KM Plan is not yet fully developed. Given the relatively short time remaining in the award, the evaluation team recommends that, in consultation with USAID, PQM de-emphasize further development of the KM plan in favor of focusing on ensuring effective information management (a component of the KM plan) that will support the overall purpose of the communications strategy and plan. Updating the current results framework and developing the narrative pathway of change should also occur simultaneously.

Continue to integrate systems thinking and system theory approaches

The evaluation team recommends that PQM adopt and integrate “systems thinking” and systems theory approaches into the “fabric” of PQM’s work. The WHO offers a robust and widely adopted systems thinking approach. This approach will help PQM align its activities and approaches related to the development and implementation of policy and regulations, information systems, and capacity building with broader health systems strengthening interventions implemented by other USAID programs (e.g., Global Health Supply Chain program and the Medicines, Technologies, and Pharmaceutical Services [MTaPS] program). Once a true systems thinking approach has been adapted to the results framework a pathway of change can be developed. Annex IV provides useful tools that can help with developing and

incorporating theory of change into PQMs work. Finally, the WHO systems thinking” approach²² may help PQM identify stakeholders that they may not have worked with in the past, measure attribution more clearly, identify inherent risks within a health system, and make clear PQM’s value-added to strengthening medicines QA systems.

Develop guidance for future investment in manufacturing

It is likely that the demand for assistance to manufacturers will only increase, particularly as African regional development and regulatory harmonization initiatives ramp up. It is also likely that there will be more stakeholders, observers, and other entities engaged at different levels than in the past. Therefore, PQM should formalize and share with these various actors its unique experience and strategy for working with manufacturers and contract research organizations, including the selection process, the provision of guidance on identifying and communicating potential risks to engagement, and systematically documenting outcomes.

Related to the above, there is also a need to further develop and formalize PQM’s in-house management tool to keep track of the technical support provided to manufacturers and per disease to monitor the progress, delays, and milestone achievement. For example, assistance to certain manufacturers was terminated because of changes to treatment regimens – this should be captured in the tracker. This will help PQM be more transparent and accountable in terms of documentation and actions regarding manufacturer “drop-out” or to help identify more rapidly when to “drop” a manufacturer, depending on situations, and be included as part of the guidance document discussed above. This tool would not be part of the PQM M&E system.

In addition, there appears to be a need to provide additional information to manufacturers to help them make the decision to engage with PQM for technical assistance. Additional attention should be given to ensuring that companies understand what these costs might be (e.g., capital investments in new structures, equipment, human resources, etc.) and assistance for how to develop a business case should be provided to manufacturers prior to assistance. While this may be considered to be a technical need beyond PQM’s scope, it may be addressed as part of the larger guidance document as a need that may be addressed by other entities that can provide this type of technical assistance.

RECOMMENDATIONS FOR USAID

Maintain level of engagement between the AOR team and PQM staff

PQM staff at all levels acknowledge the AOR team’s good communication and invaluable support. This includes the AOR team providing information and guidance on USAID policies and priorities, as well as insights on interagency initiatives to combat falsified and substandard medicines.

Similarly, PQM has been able to share information about important developments in the field with the AOR team and supported USAID’s important role in the global arena with respect to quality medicines for public health. The benefits of this mutually supportive relationship cannot be overestimated and reflects the spirit of the cooperative agreement. However, for efficiency and effectiveness, the AOR must also interface between USAID teams and PQM on top-line matters of common vision and key outcomes/results.

Increase engagement with all health element teams

USAID health element teams tend to work in silos for a number of reasons, which makes it difficult for relevant information to cross teams. PQM has not been immune to this challenge. Although some of the management changes are likely to help overcome the challenges of ensuring that strategic information is shared, the AOR team has proactively helped PQM by agreeing to support joint work plan reviews with health element teams. The AOR team should continue this approach, especially as health elements begin

²² WHO. 2009. Systems Thinking for Health System Strengthening. <http://www.who.int/alliance-hpsr/systemsthinking/en/>

to focus on new opportunities through regional development initiatives, including regional regulatory harmonization initiatives in Africa and Asia.

An important finding from PQM's work to increase the supply of key public health commodities is the need to better manage manufacturer expectations. This includes expectations related to financial commitments that may be required of them, as well as the likelihood of success. Although there may be different motivations behind the manufacturers' expressions of frustration with PQM on this issue, there is an argument for having the program focus only on technical considerations while another business development entity (e.g., a USAID partner or local entity) is engaged to provide complementary assistance on business decision-making and planning, including, if possible, identification of needed financial resources. It is recommended that the AOR team discuss PQM's experiences with the health element teams and explore if – and if so, how – this challenge may need to be addressed in the future.

Increase presence at high-level global and regional stakeholder meetings

While USAID is aware of the various global and regional initiatives regarding medicine quality and regulatory systems strengthening, and is a well-recognized and a valued partner, it has been notably less present in important fora than its counterparts, including World Bank, WHO, the U.K. Department for International Development, the Swiss Agency for Development and Cooperation, the Norwegian Agency for Development Cooperation, and the European Union/European Commission, would like and expect. Although to some extent PQM can, and does, act as the “eyes and ears” of USAID, it does not have the authority to make any decisions about how USAID should engage at the global level. USAID should be more present and be prepared to declare how it intends to contribute to these ongoing and in some case emerging initiatives.

ANNEX I. SCOPE OF WORK

Assignment #: 444 [assigned by GH Pro]

Global Health Program Cycle Improvement Project (GH Pro)

Contract No. AID-OAA-C-14-00067

EVALUATION OR ANALYTIC ACTIVITY STATEMENT OF WORK (SOW)

Date of Submission: 8/2/2017

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INSTRUCTIONS: Complete this template in MS Word to develop a SOW an evaluation, assessment, or other analytic activity. Please be as thorough as possible in completing this SOW. Your GH Pro technical advisor and project management team will assist you in finalizing your SOW.

Some of the sections below have been pre-populated with information that is common to most analytic activities. Please review these details and edit as needed to fit the needs of your specific analytic activity.

Refer to the USAID [How-To Note: Evaluation SOW](#) and the [Evaluation SOW: Good Practice Examples](#) when developing your SOW.

I. TITLE: Promoting the Quality of Medicines (PQM) Mid-Term Evaluation

II. Requester / Client

☒ USAID/Washington

Office/Division: Bureau for Global Health (GH) / Office of Health Systems (OHS)

☐ USAID Country or Regional Mission

Mission/Division: _____ / _____

III. Funding Account Source(s): (Click on box(es) to indicate source of payment for this assignment)

☐ 3.1.1 HIV

☐ 3.1.4 PIOET

☐ 3.1.7 FP/RH

☐ 3.1.2 TB

☐ 3.1.5 Other public health threats

☐ 3.1.8 WSSH

☐ 3.1.3 Malaria

☐ 3.1.6 MCH

☐ 3.1.9 Nutrition

☒ 3.2.0 Other (specify): Office of Health Systems

IV. Cost Estimate: _____ \$(Note: GH Pro will provide a cost estimate based on this SOW)

V. Performance Period

Expected Start Date (on or about): October 9, 2017

Anticipated End Date (on or about): March 30, 2018

VI. Location(s) of Assignment: (Indicate where work will be performed)

The Evaluation Team will meet with AOR Team, USAID Headquarters staff, PQM team members, and appropriate partners in Washington, DC, and will visit 2-3 PQM countries, such as Indonesia, Ethiopia, and Nigeria, to be determined by USAID/GH/OHS. One or more members of the team will visit Geneva to meet with key stakeholders and partners.

VII. Type of Analytic Activity (Check the box to indicate the type of analytic activity)

EVALUATION:

☒ Performance Evaluation (Check timing of data collection)

☒ Midterm ☐ Endline ☐ Other (specify): _____

Performance evaluations focus on descriptive and normative questions: what a particular project or program has achieved (either at an intermediate point in execution or at the conclusion of an implementation period); how it is being implemented; how it is perceived and valued; whether expected results are occurring; and other questions that are pertinent to program design, management and operational decision making. Performance evaluations often incorporate before-after comparisons, but generally lack a rigorously defined counterfactual.

☐ Impact Evaluation (Check timing(s) of data collection)

☐ Baseline ☐ Midterm ☐ Endline ☐ Other (specify): _____

Impact evaluations measure the change in a development outcome that is attributable to a defined intervention; impact evaluations are based on models of cause and effect and require a credible and rigorously defined counterfactual to control for factors other than the intervention that might account for the observed change. Impact evaluations in which comparisons are made between beneficiaries that are randomly assigned to either a treatment or a control group provide the strongest evidence of a relationship between the intervention under study and the outcome measured.

OTHER ANALYTIC ACTIVITIES

☐ Assessment

Assessments are designed to examine country and/or sector context to inform project design, or as an informal review of projects.

☐ Costing and/or Economic Analysis

Costing and Economic Analysis can identify, measure, value and cost an intervention or program. It can be an assessment or evaluation, with or without a comparative intervention/program.

☐ Other Analytic Activity (Specify)

PEPFAR EVALUATIONS (PEPFAR Evaluation Standards of Practice 2014)

Note: If PEPFAR funded, check the box for type of evaluation

☐ **Process Evaluation** (Check timing of data collection)

☐ Midterm

☐ Endline

☐ Other (specify): _____

Process Evaluation focuses on program or intervention implementation, including, but not limited to access to services, whether services reach the intended population, how services are delivered, client satisfaction and perceptions about needs and services, management practices. In addition, a process evaluation might provide an understanding of cultural, socio-political, legal, and economic context that affect implementation of the program or intervention. For example: Are activities delivered as intended, and are the right participants being reached? (PEPFAR Evaluation Standards of Practice 2014)

☐ **Outcome Evaluation**

Outcome Evaluation determines if and by how much, intervention activities or services achieved their intended outcomes. It focuses on outputs and outcomes (including unintended effects) to judge program effectiveness, but may also assess program process to understand how outcomes are produced. It is possible to use statistical techniques in some instances when control or comparison groups are not available (e.g., for the evaluation of a national program). Example of question asked: To what extent are desired changes occurring due to the program, and who is benefiting? (PEPFAR Evaluation Standards of Practice 2014)

☐ **Impact Evaluation** (Check timing(s) of data collection)

☐ Baseline

☐ Midterm

☐ Endline

☐ Other (specify):

Impact evaluations measure the change in an outcome that is attributable to a defined intervention by comparing actual impact to what would have happened in the absence of the intervention (the counterfactual scenario). IEs are based on models of cause and effect and require a rigorously defined counterfactual to control for factors other than the intervention that might account for the observed change. There are a range of accepted approaches to applying a counterfactual analysis, though IEs in which comparisons are made between beneficiaries that are randomly assigned to either an intervention or a control group provide the strongest evidence of a relationship between the intervention under study and the outcome measured to demonstrate impact.

☐ **Economic Evaluation** (PEPFAR)

Economic Evaluations identifies, measures, values and compares the costs and outcomes of alternative interventions. Economic evaluation is a systematic and transparent framework for assessing efficiency focusing on the economic costs and outcomes of alternative programs or interventions. This framework is based on a comparative analysis of both the costs (resources consumed) and outcomes (health, clinical, economic) of programs or interventions. Main types of economic evaluation are cost-minimization analysis (CMA), cost-effectiveness analysis (CEA), cost-benefit analysis (CBA) and cost-utility analysis (CUA). Example of question asked: What is the cost-effectiveness of this intervention in improving patient outcomes as compared to other treatment models?

VIII. BACKGROUND

If an evaluation, Project/Program being evaluated:

Project Title:	Promoting the Quality of Medicines (PQM) Program
Award Number:	GHS-A-00-09-00003
Award/Contract Dates:	9/18/2009 – 9/17/2019
Project Funding:	\$110 million ceiling
Implementing Organization(s):	U.S. Pharmacopeial Convention (USP)
Project AOR:	Bob Emrey

Background of project/program/intervention:

Background:

The USAID Promoting the Quality of Medicines (PQM) program is a 10-year, centrally managed cooperative agreement with a \$110 million ceiling, under award number GHS-A-00-09-00003. The program awardee is the U.S. Pharmacopeial Convention (USP). PQM is managed by the Office of

Health Systems (OHS) and accepts both USAID Washington and Mission funding from ID, MCHN, OHA, and PRH, including for malaria (30%), tuberculosis (41%), HIV (13%), maternal and child health and nutrition (12%), and neglected tropical disease (2%). PQM has received field support from 2 regions and 29 country missions, and has provided technical assistance to 34 countries around the world. The breadth and depth of work across countries and regions depends on country context and client (whether USAID Washington or USAID Country Mission) requests. However, much of programs work with manufacturers is supported with USAID Washington funding (directed core).

Context

USAID has long recognized that access to quality-assured essential medicines and other health commodities is critical to achieving improved health outcomes. Over the past three decades, USAID has financed a range of projects and programs to strengthen pharmaceutical management systems to improve access to medicines- from large-scale global programs to smaller scale Mission bilateral programs. These programs have addressed a wide spectrum of issues, including contraceptive availability, logistics and supply systems development, provision of unbiased drug information, and promotion of the rational use of medicines. In this context, the importance of medicines quality assurance has increasingly gained attention and USAID has become progressively more engaged in targeted activities to strengthen medicines quality assurance in support of the health program elements.

History

PQM was designed to function as USAID's primary mechanism to help assure the quality, safety, and efficacy of medicines of relevance to USAID health programs and was the Agency's response to the growing development challenge posed by substandard and falsified medicines worldwide. Quality-assured, safe, and efficacious medicines are essential to achieve desired health outcomes. Sub-standard and falsified medicines increase morbidity and mortality because they can cause treatment failure and adverse reactions and contribute to antimicrobial resistance (AMR). They thus represent not only a waste of scarce resources but also a substantial risk to public health. They further risk undermining decades of health investments and achievements in health outcomes.

Using a systems-based approach, PQM provides technical assistance informed by current regulatory quality assurance (QA)/quality control (QC) best practices, fosters sustainability by linking to regional and national health and pharmaceutical strategies, attains partner buy-in and commitment, leverages regional harmonization initiatives, addresses financing and human resources constraints, and advocates for accountability and transparency. Importantly, PQM aims to sustainably strengthen systems instead of providing temporary "systems support". For example, it is possible to artificially improve system performance (e.g., increase the number medicines tested for quality) but to have this performance collapse when outside support is removed.

The *goal* of PQM is to strengthen medicines quality assurance systems to sustainably ensure the quality and safety of medical products and protect public health. This is accomplished by strengthening medicines quality assurance and quality control systems in developing countries focusing on the quality control, production, distribution, and inspections of local and international pharmaceutical manufacturers.

Achieving the PQM's goal is dependent on achieving several intermediate results (IR) and sub-IRs. The activities under the intermediate results not only contribute to the strengthening medicines quality assurance systems in general but they often also feed into supporting the Global Health Bureau's different sub-elements and pathways.

The three PQM result areas are:

- (1) *Strengthen medical product quality assurance systems in developing countries.* A key obstacle to promoting quality-assured medicines and combating substandard and falsified products in developing countries is the lack of institutional, financial, technical and human resource capacity among medicines regulatory systems to protect their supply chains. Medicines quality assurance depends to a large extent on the capacity of national authorities – in essence, each country needs a capable authority to safeguard the quality, safety, and efficacy of the medicines in the market. This forms the basis for the first IR and first component of the project, namely to strengthen the drug quality assurance systems in developing countries. In order to achieve this IR, it is necessary to address the various points along the pharmaceutical supply system where quality can be affected. This includes, for example, ensuring adequate quality assurance considerations in registration, training national quality control laboratories in Good Laboratory Practices, and/or introducing a post-marketing surveillance system and/or pharmacovigilance network. Furthermore, South-South collaboration and support to strengthening national quality assurance systems can play an important role in strengthening national capacity.
- (2) *Increase the supply of quality-assured priority medicines.* In many instances, quality-assured medicines are not available and Ministries of Health, health facilities and/or patients have little choice but to use medicines that have not necessarily undergone rigorous regulatory oversight. This is currently and most strikingly the case for 2nd line TB medicines for which the lack of quality-assured products and WHO prequalified manufacturers continues to be a barrier to maximizing positive health outcomes. In general, and as mentioned before, without quality-assured, efficacious, and safe medicines, the impact of other health investments is negated. This forms the basis for the second IR, namely to increase the supply of quality-assured medicines of direct relevance to priority USAID health programs (including TB, MNCH, NTD, PMI, and PEPFAR). To do this, PQM collaborates with the World Health Organization (WHO) and other agencies to build capacity of local manufacturers that produce essential medicines or the active ingredients and wish to expand to local, regional, or global markets. The program provides technical support to enable manufacturers to comply with international standards for Good Manufacturing Practices, allowing the manufacturer to build stronger quality-assurance systems and satisfy medicines regulatory requirements for marketing authorization and procurement. The bulk of PQM's work aimed at expanding the pool of pre-qualified drug manufacturers and products is supported largely by core health element funding, although selected Missions are also providing funds to support local manufacturers.
- (3) *Increase the utilization of medical product quality information for decision-making.* Poor-quality medicines pose a grave threat to patients in developing countries, but this is a largely unknown problem to the public, something that USAID, PQM, and national authorities are working diligently to tackle. PQM uses a variety of methods to raise awareness among local partners and civil society about the potential dangers of substandard medicines and the importance of medicines quality assurance in terms of health outcomes and containment of AMR, each tailored to best reach the individual audience. PQM uses and exchanges tools, best practices, data, and lessons learned at local, regional, and global levels related to medicines quality. For example, PQM assists countries in implementing Medicines Quality Monitoring (MQM) programs where little capacity exists, and works to enhance existing MQM systems through a wide range of activities. PQM collaborates with a country's medicine regulatory agency and national health programs to establish (or fortify) a system to regularly examine the quality of medicines circulating in its markets. Several steps are involved in setting up this MQM program, which takes into account the country's needs and resources. Having medicines quality information is essential in order to increase the ability of local partners to improve on MQM systems over time. USP's Medicines Quality Database (MQDB) currently contains the results of MQM activities established through PQM collaborations, and the information included is approved for dissemination by the authorities

of participating countries. The Poor-Quality Medicines Alert contains information from multiple sources, either reported to or identified by PQM within the last year.

Increased awareness and data must be coupled with the use of this information to reduce the presence of falsified, substandard, and unapproved medicines and to ensure enforcement actions in response to the presence of such medical products. While it is essential that countries strengthen their national quality assurance systems, combating substandard and falsified medicines also requires interventions at regional and international level.

With the ceiling increase and extension, PQM was requested also to continue to develop and robust health systems strengthening approach in its technical assistance to medicine regulatory authorities (MRA), national quality control laboratories (NQCLs), and local pharmaceutical manufacturers where the focus was on building quality assurance systems in collaboration with national stakeholders. In addition, it was intended for PQM to continue to provide technical assistance through regional bodies and networks to maximize the impact of its interventions.

As stated previously, PQM activities are determined by client priorities (whether USAID Washington or Mission funding) in approved work plans, taking into account the systems strengthening approach described above. Client priorities are commonly determined through interaction with stakeholders (e.g., host country government counterparts). The effectiveness of PQM in implementing its technical approach within this context and the lessons learned this presents to the Agency within the areas of medical product quality assurance systems strengthening is the subject of this evaluation.

Relevant projects that were operational at the time that PQM was designed and awarded, including those managed from other offices within the Bureau of Global Health, are summarized below. Those that have since closed and where follow-on projects have been awarded are also noted; these follow-up projects continue to be relevant to PQM's scope.

- **The Strengthening Pharmaceutical Systems (SPS) Program (2005-2011)** A “first generation” pharmaceutical systems strengthening project, also managed by MSH, the SPS project was a predominantly field-based project and provided technical support that embraced supply chain management as well as other technical areas with a focus on the expansion and scale-up of prevention and treatment programs. Building on the solid conceptual and empirical foundation for understanding pharmaceutical systems created by the predecessor projects, Rational Pharmaceutical Management (RPM) and RPM Plus, SPS was at the forefront in developing new tools and approaches supporting all the health elements, including access to medicines and pharmaceutical services for post-partum hemorrhage, childhood diarrhea, acute respiratory infections, malaria, TB, and HIV/AIDS programs. A Leader with Associates cooperative agreement, SPS provided guidance to all the major global health initiatives including the Global Fund, the Global Drug Facility (GDF), the Green Light Committee (GLC), Roll Back Malaria, and the Stop TB Partnership. It also implemented up to 20 country programs, with four associate awards. SPS and predecessor projects were managed through the HIDN and SIAPS was designed to be the logical follow-on to the SPS project, with greater emphasis on integration with larger health systems strengthening frameworks. SPS ended in 2011 at which time **the Systems for Improved Availability of Pharmaceuticals and Services Program (SIAPS) (2011-2018)** continued this work. SIAPS is scheduled to close in March 2018; a successor program **(Medicines, Technologies, and Pharmaceutical Services (MTaPS))** is currently in the procurement process and expected to be awarded in March 2018.
- **Supply Chain Management Systems (SCMS) project (2009-2015).** The SCMS contract was designed to provide one-stop shopping for HIV/AIDS-related commodities and supplies for HIV/AIDS programs funded by PEPFAR. Managed by the OHS Division of Supply Chain for Health,

SCMS also provides technical assistance to national supply chains to ensure availability of ARVs and related commodities, including support for quantification, warehousing, and distribution. Activities include training and development of information systems to ensure long-term sustainability of distribution systems in participating countries.

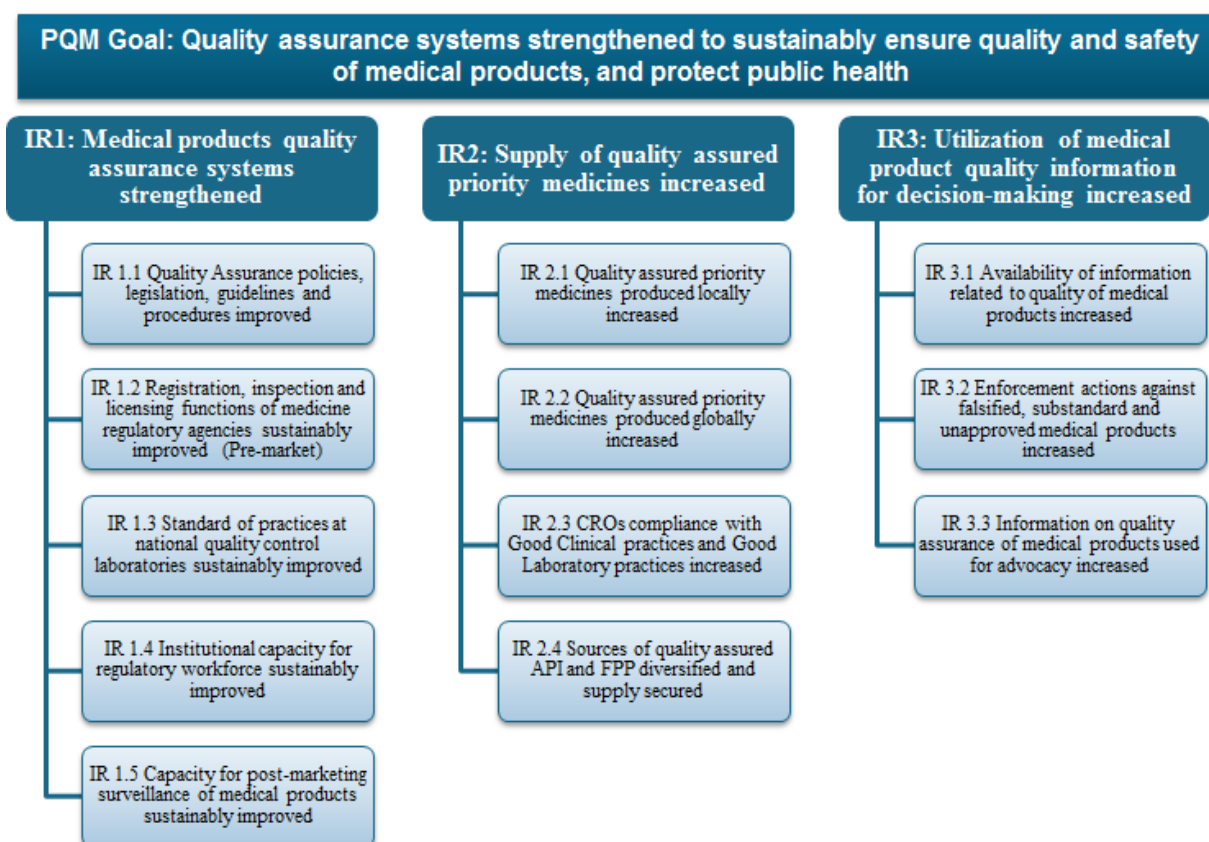
- **USAID|DELIVER II project (2009-2015).** An indefinite quantity contract (IQC) with eight task orders, the USAID|DELIVER project is managed from the PRI and implemented by JSI. USAID|DELIVER, the most recent of a series of similar projects that has been in existence for over a decade, has developed and offers training courses on supply chain management and has conducted seminal research on modeling supply chain development and assessments of alternative supply chain systems, including innovative approaches to sustainability. Through the various task orders and with field support, the project supports the actual procurement of commodities for reproductive health and family planning and malaria, including quantification, warehousing, and distribution. Technical assistance is also provided to partner country governments and non-governmental and private voluntary organizations to develop supply chains for essential health supplies.
- **The Global Health Supply Chain Program.** Both SCMS and the USAID|DELIVER projects ended in September 2016, and were replaced by follow-on project managed under a new architecture within the Bureau for Global Health that includes a suite of intersecting contracts, which are outlined below:
 - **Global Health Supply Chain Procurement and Supply Management (GHSC-PSM)** single-award Indefinite Delivery, Indefinite Quantity (IDIQ) Contract was awarded in April 2015 to Chemonics International Inc. The purpose of the GHSC-PSM IDIQ is to ensure uninterrupted supply of health commodities to prevent suffering, save lives, and strengthen supply chain systems in low- and middle-income countries. Four task orders were awarded under the IDIQ: Task Order 1 for HIV/AIDS, Task Order 2 for Malaria, Task Order 3 for Population and Reproductive Health (PRH), and Task Order 4 for Maternal, Newborn, and Child Health (MNCH). **Global Health Supply Chain Technical Assistance (GHSC-TA)** multiple-award IDIQ was awarded in March 2015 to four prime partners: Axios International, Inc. (small business), Chemonics International Inc., Logistics Management Institute (LMI), and PricewaterhouseCoopers. These awards aim to strengthen country management of health commodities, providing technical assistance to ensure the long-term availability of health commodities in public and private health services worldwide. These awards serve all health elements (HIV, family planning, malaria, maternal and child health (MCH), TB, etc.).
 - **Global Health Supply Chain Quality Assurance (GHSC-QA)** Contract was awarded in January 2015 to FHI 360 and serves as the primary vehicle through which USAID assures the quality of health commodities procured with USAID funding in support of USAID global health programs by implementing an overarching QA program and risk-based quality-control strategy. GHSC-QA is also engaged with other international stakeholders within the quality assurance arena and provides short-term technical assistance to the field as requested for ongoing QA systems strengthening.
 - **Global Health Supply Chain Rapid Test Kits (GHSC-RTK)** Contract was awarded in February 2015 as a small business set aside to Remote Medical International (RMI) and serves as the singular means of procuring HIV Rapid Test Kits (RTKs) within the GHSC Program. The primary objective of this Contract is to ensure the availability of approved HIV RTKs using a global procurement strategy.
 - **Global Health Supply Chain Business Intelligence & Analytics (GHSC-BI&A).** Contract was awarded in May 2014 to Intellicog. This Contract serves as a primary vehicle

through which USAID houses program data, performs analysis, and understands data trends in support of global health programs. In addition, dashboards and data visualizations are created that show trends at the global and country levels. The data collected is harmonized across supply chain contractors to ensure the programs run seamlessly.

- **Global Health Supply Chain Project Last Mile (GHSC-PLM)** was awarded in June 2014 to an alliance between USAID, the Coca-Cola Company, the Global Fund to Fight AIDS Tuberculosis and Malaria (GFATM), and the Bill and Melinda Gates Foundation. The objective of GHSC-PLM is to improve the delivery of medicines in developing country markets and, in particular, to those citizens residing in and around the last mile of the medical supply chain by leveraging Coca-Cola's business intelligence in supply chain and marketing.

Strategic or Results Framework for the project/program/intervention (*paste framework below*)

If project/program does not have a Strategic/Results Framework, describe the theory of change of the project/program/intervention.



What is the geographic coverage and/or the target groups for the project or program that is the subject of analysis?

PQM works globally, with an in-country office in: Ethiopia, Indonesia, Philippines, and Nigeria. Activities are also conducted in Angola, Bangladesh, Benin, Burma, Burkina Faso, Burundi, Cambodia, Ghana, Guinea, Kazakhstan, Kenya, Liberia, Madagascar, Malawi, Mali, Mozambique, Pakistan, Senegal, Uzbekistan, Vietnam, West Bank/Gaza, and selected countries in the Latin American and Caribbean Region (Bolivia, Brazil, Colombia, Ecuador, Guatemala, Guyana, Paraguay, Peru, and Suriname). In the recent past, activities were implemented in Cambodia, and, Vietnam.

IX. PURPOSE, AUDIENCE & APPLICATION

A. Purpose: Why is this evaluation or analysis being conducted (purpose of analytic activity)? Provide the specific reason for this activity, linking it to future decisions to be made by USAID leadership, partner governments, and/or other key stakeholders.

The purpose of this performance evaluation is to provide the United States Agency for International Development (USAID) Bureau for Global Health (GH) Office of Health Systems (OHS) with an objective assessment of USAID's Promoting the Quality of Medicines (PQM), a centrally-managed ten-year cooperative agreement (GHS-A-00-09-00003) between USAID and the United States Pharmacopeial Convention (USP), managed by OHS. PQM was originally awarded September 18, 2009, and scheduled to run through September 17, 2014 with a ceiling of \$35 million. The program received a costed extension increasing the ceiling to \$110 million and is now scheduled to close on September 17, 2019. While PQM does not have a project monitoring, evaluation, and learning (MEL) plan, this evaluation is being conducted to help ensure accountability to stakeholders and to improve project outcomes.

Specifically, this evaluation is being conducted to:

- **Determine the effectiveness of PQM's program implementation in achieving the project goal and intermediate results**, including its ability to generate evidence that implementing its approach has contributed to strengthening quality assurance systems in low- and middle-income countries (LMICs), and assess how the project's management structure, processes, and staffing patterns have helped or hindered progress toward achieving the project goal and IRs. This includes evaluation of the level of client satisfaction, including satisfaction of GH Offices/Health Elements, Missions, and other clients/partners/counterparts with progress toward achieving work plan objectives and prioritized recommendations that can be feasibly incorporated into the remainder of the existing PQM program;
- Identify accomplishments and challenges in implementing to improve efficiency and opportunities for PQM program implementation adjustments, both in terms of current technical activity and program management; and
- **Provide recommendations to USAID for potential future investments in medicines quality assurance systems strengthening**, whether centrally managed or bilateral, to comprehensively address the areas of technical focus related to medicines quality assurance systems strengthening necessary to sustainably achieve desired health outcomes. Identify issues in medicines quality systems strengthening that future projects may encounter and need to address.

This evaluation will take place approximately four-fifths of the way through the expected performance period of PQM. The assessment will gather and synthesize information from multiple sources, including the GH Bureau Office of Infectious Disease, (ID), Office of HIV/AIDS (OHA)/PEPFAR, Office of Population and Reproductive Health (PRH), Office of Maternal, Newborn, and Child Health

(MNCH), Missions, USAID Agreement Officer Representative (and team), and other key stakeholders, as detailed in the section on Key Informant interviews.

B. Audience: Who is the intended audience for this analysis? Who will use the results? If listing multiple audiences, indicate which are most important.

While the primary audience for the evaluation is the Office of Health Systems and the Bureau for Global Health leadership. Findings may also be used by PQM management to make adjustments in program implementation, Missions, and other peripheral stakeholders.

C. Applications and use: How will the findings be used? What future decisions will be made based on these findings?

Management decisions that will be made using evaluation data include:

1. Whether the technical focus areas of PQM continue to be relevant to the Agency and whether additional technical areas should be included in a potential new program design.
2. Opportunities for PQM program implementation improvements in technical activities and/or program management.

X. Evaluation/Analytic Questions & Matrix:

- a) Questions should be: a) aligned with the evaluation/analytic purpose and the expected use of findings; b) clearly defined to produce needed evidence and results; and c) answerable given the time and budget constraints. Include any disaggregation (e.g., sex, geographic locale, age, etc.), they must be incorporated into the evaluation/analytic questions. **USAID policy suggests 3 to 5 evaluation/analytic questions.**
- b) List the recommended methods that will be used to collect data to be used to answer each question.
- c) State the application or use of the data elements towards answering the evaluation questions; for example, i) ratings of quality of services, ii) magnitude of a problem, iii) number of events/occurrences, iv) gender differentiation, v) etc.

	Evaluation Question	Method & Data Source
1	What is the effectiveness of the project's implementation of in-country (field support) work?	Key informant interviews; assessment of progress reports and technical products; analyses, such as frequency counts and simple spreadsheets, of project inputs, outputs, and accomplishments.
2	What is the effectiveness of the project's implementation of USAID Washington-funded (directed core funds or health element) work?	Key informant interviews; assessment of progress reports and technical products; analyses, such as frequency counts and simple spreadsheets, of project inputs, outputs, and accomplishments.
3	What is PQM's ability to demonstrate their work has contributed to the sustainable strengthening of medicines quality assurance systems?	Key informant interviews; assessment of progress reports and technical products; analyses, such as frequency counts and simple spreadsheets, of project inputs, outputs, and accomplishments.
4	Do the technical focus areas of PQM continue to be relevant to the Agency and should additional technical areas be included in a new program design?	Key informant interviews; assessment of progress reports and technical products; analyses, such as frequency counts and simple

		spreadsheets, of project inputs, outputs, and accomplishments.
5	How is PQM advancing the medicines quality assurance agenda and providing global technical leadership in medicines quality assurance?	Key informant interviews; assessment of progress reports and technical products; analyses, such as frequency counts and simple spreadsheets, of project inputs, outputs, and accomplishments.
6	How have PQM's management structure, processes, and staffing patterns helped or hindered progress towards achieving the project's goal and results?	Key informant interviews; assessment of progress reports and technical products; analyses, such as frequency counts and simple spreadsheets, of project inputs, outputs, and accomplishments.

Other Questions [OPTIONAL]

(Note: Use this space only if necessary. Too many questions leads to an ineffective evaluation or analysis.)

XI. Methods: Check and describe the recommended methods for this analytic activity. Selection of methods should be aligned with the evaluation/analytic questions and fit within the time and resources allotted for this analytic activity. Also, include the sample or sampling frame in the description of each method selected.

The Evaluation Team will be based in DC to work closely with the PQM/USAID team, but some work can be done remotely as determined during the Team Planning Meeting. Additionally, there will be field visits to 2-3 country projects. Considerations for country selection include: scope of the project (in terms of breadth of technical areas covered), complexity/number of health elements supporting technical activities, size of the project (in terms of value), and interest of the Mission in participating in the evaluation. Countries with such comprehensive projects that may be considered for field visits include Indonesia, Ethiopia, and Nigeria.

■ Document and Data Review (*list of documents and data recommended for review*)

This desk review will be used to provide background information on the project/program, and will also provide data for analysis for this evaluation. Documents and data to be reviewed include:

- PQM's Monitoring and Evaluation Plan (including the project's results)
- Current funding profile
- The RFA, PQM proposal, PQM cooperative agreement, project M&E Plan, country M&E plans, quarterly and annual reports, trip reports, other financial tracking reports, Knowledge Management strategy, success stories, PQM training materials and evaluations of PQM trainings, etc.
- Work plans (core- and field support-funded). Note that PQM receives funding from a variety of sources, including directed core health element funds from virtually all of the health elements as well as cross-bureau core funds and field support funds. Activities are implemented as global technical leadership, research and innovation, or support to the field.
- PQM self-assessment reports (where available)
- The Medicine Quality Database and the Poor-Quality Medicines ALERT system.
- PQM draft paper: Risk Based Approach
- Monitoring the Quality of Medicines: Results from Africa, Asia, and South America. The American Journal of Tropical Medicine and Hygiene, Volume 92, Issue 6_Suppl, Jun 2015

Additional project-related information and technical reports can be found at the PQM project website (<http://usp-pqm.org>) and on the USAID Development Experience Clearinghouse (<https://dec.usaid.gov>).

■ **Secondary analysis of existing data** (*This is a re-analysis of existing data, beyond a review of data reports. List the data source and recommended analyses*)

Data Source (existing dataset)	Description of data	Recommended analysis
PQM data in Newdea	Newdea is PQM's online system; used to collect and report information on progress toward objectives and goal.	No significant statistical analysis will be required. Data is organized in such a way that the indicator and objective for which it is being collected will be explicit for the evaluators.
Data collected as part of specific studies (i.e. diversion studies).	Information that is part of technical reports; will be made available to the evaluators as part of the background information.	No significant statistical analysis will be required. Data is organized in such a way that the indicator and objective for which it is being collected will be explicit for the evaluators.

■ **Key Informant Interviews** (*list categories of key informants and purpose of inquiry*)

A list of interviewees and key stakeholders will be provided by USAID prior to the assignment's inception. During the Team Planning Meeting, the list will be finalized in consultation with the USAID Mission and Washington DC-based leads from malaria, HIV/AIDS, TB, NTD, and MCHN for each country.

The evaluation team will conduct in-depth key informant and/or group interviews, at a minimum, with the following organizations/staff:

- PQM project staff (senior management as well as technical and regional leads)
- USP leadership (including senior management of Global Health Programs (GHP))
- USAID Mission activity managers and health officers in selected countries with PQM field support (see below regarding field survey and field visits)
- USAID Washington health element point persons for PQM for MCH, malaria, TB, NTDs, HIV/AIDS
- Subject matter experts, outside stakeholders, and other identified partners, including, but not limited to:
 - World Health Organization (WHO) – Department of Essential Medicines and Health Products
 - Stop TB Partnership Secretariat/WHO
 - Pan-American Health Organization (PAHO)
 - US Food and Drug Administration -- Office of Global Regulatory Operations and Policy
 - Global Fund to Fight AIDS, Tuberculosis, and Malaria
 - Stop TB Partnership - Global Drug Facility (<http://www.stoptb.org/gdf/>)
 - The World Bank
 - USP–Ghana, Center for Pharmaceutical Advancement and Training (CePAT) (<http://www.usp.org/about/usp-offices/usp-ghana>)

- Nigeria National Agency for Food and Drug Administration and Control (NAFDAC) (<http://www.nafdac.gov.ng/>)
- African Medicines Regulatory Harmonisation (AMRH) (<http://www.nepad.org/content/african-medicines-regulatory-harmonisation-armh-programs>)
- East African Community (EAC) (<http://www.eac.int/about/overview>)
- Ecumenical Pharmaceutical Network (EPN) (<http://www.epnetwork.org/index.php/en/>)
- University of Washington – Global Medicines Program (<https://sop.washington.edu/departments-of-pharmacy/global-medicines-program/>)

During **Field Visits**, the following interviews will be conducted:

- PQM staff
- USAID Mission activity managers
- Key local stakeholders from the Ministry of Health and other relevant institutions

☐ **Focus Group Discussions** (*list categories of groups, and purpose of inquiry*)

☒ **Group Interviews** (*list categories of groups, and purpose of inquiry*)

Some of the key informants listed above can be clustered together in a group interview (providing this does not create a space where interviewees do not feel comfortable speaking freely).

☐ **Client/Participant Satisfaction or Exit Interviews** (*list who is to be interviewed, and purpose of inquiry*)

☒ **Survey** (*describe content of the survey and target responders, and purpose of inquiry*)

A brief survey will be conducted among field Missions where PQM has worked to gather information on PQM technical performance and client satisfaction and determine the extent to which the project's technical focus and IRs continue to be relevant for the achievement of Mission priorities in addressing country health system needs. The survey will solicit input about technical areas of concern related to medicines quality assurance systems strengthening.

Web-based survey tools (e.g., Survey Monkey) are recommended for this. If the sample size is small enough, the survey may be administered by phone to ensure a better response rate. It may be necessary to develop this survey in multiple languages.

XII. HUMAN SUBJECT PROTECTION

The Analytic Team must develop protocols to insure privacy and confidentiality prior to any data collection. Primary data collection must include a consent process that contains the purpose of the evaluation, the risk and benefits to the respondents and community, the right to refuse to answer any question, and the right to refuse participation in the evaluation at any time without consequences. Only adults can consent as part of this evaluation. **Minors cannot be respondents to any interview or survey, and cannot participate in a focus group discussion without going through an IRB.** The only time minors can be observed as part of this evaluation is as part of a large community-wide public event, when they are part of family and community in the public setting. During the process of this evaluation, if data are abstracted from existing documents that include unique identifiers, data can only be abstracted without this identifying information.

An Informed Consent statement included in all data collection interactions must contain:

- Introduction of facilitator/note-taker
- Purpose of the evaluation/assessment
- Purpose of interview/discussion/survey
- Statement that all information provided is confidential and information provided will not be connected to the individual
- Right to refuse to answer questions or participate in interview/discussion/survey
- Request consent prior to initiating data collection (i.e., interview/discussion/survey)

XIII. ANALYTIC PLAN

Describe how the quantitative and qualitative data will be analyzed. Include method or type of analyses, statistical tests, and what data it to be triangulated (if appropriate). For example, a thematic analysis of qualitative interview data, or a descriptive analysis of quantitative survey data.

The evaluation team will be responsible for coordinating the data analysis. The analysis will use social science approaches to answer the evaluation questions outlined above. The Evaluation Team should propose a detailed analysis plan that would generate robust evidence needed to answer the evaluation questions. Each team member will participate in the analysis and contribute to the interpretation of the data, as their area of specialty allows.

The evaluation will utilize both qualitative and quantitative data related to PQM in order to answer the evaluation question stated within this SOW.

Quantitative data will be analyzed primarily using descriptive statistics. Data will be stratified by demographic characteristics, such as location and sex, when appropriate. Other statistical test of association (i.e., odds ratio) and correlations will be run as appropriate. In the report the Evaluators will describe the statistical tests used.

Thematic review of qualitative data will be performed, connecting the data to the evaluation questions, seeking relationships, context, interpretation, nuances, homogeneity, and outliers to better explain what is happening and the perception of those involved. Qualitative data will be used to substantiate quantitative findings, provide more insights than quantitative data can provide, and answer questions where other data do not exist.

Use of multiple methods that are quantitative and qualitative, as well as existing data (e.g., project performance indicator data and county specific DHS) will allow the Team to triangulate findings to produce more robust evaluation results.

XIV. ACTIVITIES

List the expected activities, such as Team Planning Meeting (TPM), briefings, verification workshop with IPs and stakeholders, etc. Activities and Deliverables may overlap. Give as much detail as possible.

Background reading/Desk review – Several documents are available for review for this analytic activity. These include the PQM RFA, proposal, annual work plans, M&E plans, quarterly progress reports, progress reports, routine reports of project performance indicator data, evaluation reports, and other project generated reports and materials. This desk review will provide background information for the Evaluation Team, and will also be used as data input and evidence for the evaluation.

Team Planning Meeting (TPM) – A three-day team planning meeting (TPM) will be held at the initiation of this assignment and before the data collection begins. The TPM will:

- Review and clarify any questions on the evaluation SOW;

- Clarify team members' roles and responsibilities;
- Establish a team atmosphere, share individual working styles, and agree on procedures for resolving differences of opinion;
- Review and finalize evaluation questions;
- Review and finalize the assignment timeline and share with other units;
- Develop data collection methods, instruments, tools and guidelines;
- Review and clarify any logistical and administrative procedures for the assignment;
- Develop a data collection plan;
- Draft the evaluation work plan for USAID's approval;
- Develop a preliminary draft outline of the team's report; and
- Assign drafting/writing responsibilities for the final report.

Evaluation Plan – By the close of the TPM, the evaluation team will prepare a detailed evaluation plan in response to SOW requirements and evaluation questions. In consultation with the USAID/GH/OHS team, the detailed evaluation plan should identify the countries for site visits and individuals and stakeholders for in-depth interviews and should include each of the proposed data collection instruments (i.e., structured interview guides, surveys, observation forms, etc.). A draft of the detailed evaluation plan and data collection instruments should be submitted to the USAID/GH/OHS team for input prior to finalization.

Briefing and Debriefing Meetings – Throughout the evaluation the Team Lead will provide briefings to USAID. The In-Brief and Debrief are likely to include the all Evaluation Team experts, but will be determined in consultation with the Mission. These briefings are:

- **Evaluation launch**, a call/meeting among the USAID, GH Pro and the Team Lead to initiate the evaluation activity and review expectations. USAID will review the purpose, expectations, and agenda of the assignment. GH Pro will introduce the Team Lead, and review the initial schedule and review other management issues.
- **In-brief with USAID/GH/OHS**, as part of the TPM. At the beginning of the TPM, the Evaluation Team will meet with USAID to discuss expectations, review evaluation questions, and intended plans. The Team will also raise questions that they may have about the project/program and SOW resulting from their background document review. The time and place for this in-brief will be determined between the Team Lead and USAID prior to the TPM.
- **Evaluation & Work Plan review briefing**. At the end of the TPM, the Evaluation Team will meet with USAID to present an outline of the methods/protocols, timeline and data collection tools. Also, the format and content of the Evaluation report(s) will be discussed.
- **In-brief with PQM** to review the evaluation plans and timeline, and for the project to give an overview of the project to the Evaluation Team.
- The Team Lead (TL) will brief the USAID **weekly** to discuss progress on the evaluation. As preliminary findings arise, the TL will share these during the routine briefing, and in an email.
- A **final debrief** between the Evaluation Team and USAID/GH/OHS will be held at the end of the evaluation to present preliminary findings to USAID/GH/OHS. During this meeting a summary of the data will be presented, along with high level findings and draft recommendations. For the debrief, the Evaluation Team will prepare a **PowerPoint Presentation** of the key findings, issues, and recommendations for selected stakeholders: one for USAID and another for USP. The evaluation team shall incorporate comments received from USAID during the debrief in the

evaluation report. A draft of the final presentations should be submitted to the AOR team prior to finalization (**Note:** *preliminary findings are not final and as more data sources are developed and analyzed these finding may change.*)

- **PQM and Stakeholder debrief/workshop** will be held following the final debrief with the USAID.GH.OHS. The Evaluation Team will discuss with USAID who should participate.

Fieldwork, Site Visits and Data Collection – The evaluation team will conduct site visits to for data collection. Selection of sites to be visited will be finalized during TPM in consultation with USAID. The evaluation team will outline and schedule key meetings and site visits prior to departing to the field.

Evaluation/Analytic Report – The Evaluation/Analytic Team under the leadership of the Team Lead will develop a report with findings and recommendations (see Analytic Report below). Report writing and submission will include the following steps:

1. Team Lead will submit draft evaluation report to GH Pro for review and formatting
2. GH Pro will submit the draft report to USAID
3. USAID will review the draft report in a timely manner, and send their comments and edits back to GH Pro
4. GH Pro will share USAID's comments and edits with the Team Lead, who will then do final edits, as needed, and resubmit to GH Pro
5. GH Pro will review and reformat the final Evaluation/Analytic Report, as needed, and resubmit to USAID for approval.
6. Once Evaluation Report is approved, GH Pro will re-format it for 508 compliance and post it to the DEC.

The Evaluation Report **excludes** any **procurement-sensitive** and other sensitive but unclassified (**SBU**) information. This information will be submitted in a memo to USIAD separate from the Evaluation Report.

Data Submission – All quantitative data will be submitted to GH Pro in a machine-readable format (CSV or XML). The datasets created as part of this evaluation must be accompanied by a data dictionary that includes a codebook and any other information needed for others to use these data. It is essential that the datasets are stripped of all identifying information, as the data will be public once posted on USAID Development Data Library (DDL).

Where feasible, qualitative data that do not contain identifying information should also be submitted to GH Pro.

XV. DELIVERABLES AND PRODUCTS

Select all deliverables and products required on this analytic activity. For those not listed, add rows as needed or enter them under “Other” in the table below. Provide timelines and deliverable deadlines for each.

Deliverable / Product	Timelines & Deadlines (Estimated)
■ Launch briefing	October 9, 2017
■ In-brief with USAID/GH/OHS	October 16, 2017
■ Evaluation & Work Plan review briefing	October 21, 2017
■ In-brief with PQM	October 23, 2017
■ Workplan with timeline, with protocol & data collection tools submitted to USAID & GH Pro	October 24, 2017

Deliverable / Product	Timelines & Deadlines (Estimated)
☒ Routine briefings	Weekly
☒ Out-brief with USAID w/ PowerPoint presentation	January 3, 2018
☒ Findings review workshop with PQM & stakeholders with Power Point presentation	January 5, 2018
☒ Draft report	Submit to GH Pro: January 19, 2018 GH Pro submits to USAID: January 26, 2018
☒ Final report	Submit to GH Pro: February 16, 2018 GH Pro submits to USAID: February 21, 2018
☒ Raw data (cleaned datasets in CSV or XML with codesheet)	February 6, 2018
☒ Report Posted to the DEC	March 30, 2018
☐ Other (specify):	

Estimated USAID review time

Number of business days USAID will need to review and/or approve the Report? 10
Business days

XVI. TEAM COMPOSITION, SKILLS AND LEVEL OF EFFORT (LOE)

Evaluation/Analytic team: When planning this analytic activity, consider:

- Key staff should have methodological and/or technical expertise, regional or country experience, language skills, team lead experience and management skills, etc.
- Team leaders for evaluations/analytics must be an external expert with appropriate skills and experience.
- Additional team members can include research assistants, enumerators, translators, logisticians, etc.
- Teams should include a collective mix of appropriate methodological and subject matter expertise.
- Evaluations require an Evaluation Specialist, who should have evaluation methodological expertise needed for this activity. Similarly, other analytic activities should have a specialist with methodological expertise.
- Note that all team members will be required to provide a signed statement attesting that they have no conflict of interest, or describing the conflict of interest if applicable.

Team Qualifications: Please list technical areas of expertise required for this activity.

A 3-4 person evaluation team is proposed; one of the members is to be designated as **team leader** and should have experience leading an evaluation team. The evaluation team should have substantial demonstrated knowledge in **health systems strengthening**, including pharmaceutical management, and **medicines quality assurance**, and in conducting project evaluations in LMICs.

All team members should participate in interviews and review all documents. Not all team members will need to travel to all field sites however all team members should be appropriately engaged to ensure the reliability of interviews data such that findings may be meaningfully analyzed and compared to inform recommendations.

Collectively, team members will need to have the following skills and experience:

- 10-12 years of experience in international public health, including the areas of health systems strengthening and pharmaceutical management.
- 5-7 years of experience in the area of medicines quality assurance systems strengthening in LMICs.
- Expertise is required for several of the following technical areas:
 - National medicines regulatory systems strengthening (medicines evaluation, inspection, and quality surveillance functions)
 - Medicines quality monitoring and control systems
 - Prequalification programs
 - International standards for Good Manufacturing Practices
 - Combatting sub-standard and falsified medicines
 - Medicines regulatory harmonization
 - Monitoring and evaluation of projects in developing countries, preferably on USAID projects/programs
- Extensive experience with conducting evaluations, assessments, and questionnaire design
- Understanding of USAID contracting of centrally funded and bilateral projects

In addition, each member should have the following skills and experience:

- An advanced degree in public health or related field
- Excellent English language skills, both written and oral
- Demonstrated knowledge of USAID policies, programs, and procedures (including USAID's evaluation policy)
- Good interpersonal communication skills and the ability to interact effectively with a diverse set of professionals.
- Ability to effectively conduct interviews, in person or by phone

The team lead will be responsible for organizing and carrying out the evaluation, communicating with the PQM/USAID management team, ensuring the quality of the questionnaire design and data collection process, and writing and editing the final assessment report.

Other Staff Titles with Roles & Responsibilities (include number of individuals needed):

Local Evaluation and Logistics Assistant is needed in each country that the Evaluation Team will visit. This individual in each country will assist Evaluation Team to set up appointments in advance of their arrival, arrange transportation and provide translation as needed for data collection. They will also provide local context to assist the Team with interpreting the data as collected.

DC-based Project Assistant will work with the team to set appointments for interviews and meetings, assist with web-based survey, and other administrative needs.

Will USAID participate as an active team member or designate other key stakeholders to as an active team member? This will require full time commitment during the evaluation or analytic activity.

☐ Yes – If yes, specify who:

☐ Some Involvement anticipated – If yes, specify who:

☒ No

Staffing Level of Effort (LOE) Matrix:

This optional LOE Matrix will help you estimate the LOE needed to implement this analytic activity. If you are unsure, GH Pro can assist you to complete this table.

- For each column, replace the label "Position Title" with the actual position title of staff needed for this analytic activity.
- Immediately below each staff title enter the anticipated number of people for each titled position.
- Enter Row labels for each activity, task and deliverable needed to implement this analytic activity.
- Then enter the LOE (estimated number of days) for each activity/task/deliverable corresponding to each titled position.
- At the bottom of the table total the LOE days for each consultant title in the 'Sub-Total' cell, then multiply the subtotals in each column by the number of individuals that will hold this title.

Level of Effort in **days** for each Evaluation/Analytic Team member

Activity / Deliverable		Evaluation/Analytic Team					
		Team Lead	Technical Expert 1	Technical Expert 2	Evaluation Specialist	DC Project Assistant	Local Evaluator
Number of persons ☐		1	1	1	1	1	3
1	Launch Briefing	0.5					
2	HTSOS Training	1	1				
3	Desk review	5	5	3	3		
4	Travel to/from DC	1	1	1			
5	In-brief with USAID/GH/OHS	1	1	1	1		
6	Team Planning Meeting	3	3	3	3		
7	Work plan briefing with USAID	0.5	0.5	0.5	0.5	0.5	
8	In-brief with PQM, including prep	1	1	1	1		
9	Finalize data collection forms & procedures for all data collectors (circulate with USAID and GH Pro for QA)	0.5	0.5		0.5		
10	Data Collection work shop (protocol orientation/training for all data collectors)	0.5	0.5		0.5		
11	Prep/Logistics for data collection	0.5	0.5		0.5	1	2
12	Data collection in US	10	10	6	2	2	
13	Field Visits: Travel and Data Collection in PQM countries	28	24	0	0	3	6 days each
	Indonesia	6	6				6
	Ethiopia	6	6				6
	Nigeria	6	6				6
	Geneva	3					
	Travel	7	6				
14	Data analysis & synthesis	5	5	3	3		
15	Travel to/from DC	1	1	1			
16	Debrief with USAID w/presentation, including prep	1	1	1	1	0.5	
17	Incorporate USAID's feedback	1	1	1	1		
18	PQM Stakeholders' workshop, including prep	1	1	1	1		
19	Draft Evaluation report	7	6	3	4		
20	GH Pro Report QC Review & Formatting						
21	Submission of draft report(s) to Mission						
22	USAID Report Review						
23	Revise report(s) per USAID comments	4.5	3	0.5	1		
24	Finalize and submit report to USAID						

Activity / Deliverable		Evaluation/Analytic Team					
		Team Lead	Technical Expert 1	Technical Expert 2	Evaluation Specialist	DC Project Assistant	Local Evaluator
25	USAID approves report						
26	Final copy editing and formatting						
27	508 Compliance editing						
28	Upload Eval Report(s) to the DEC						
Sub-Total LOE		73	66	26	23	7	8
Total LOE		73	66	26	23	7	24

If overseas, is a 6-day workweek permitted ☒ Yes ☐ No

Travel anticipated: List international and local travel anticipated by what team members.

Indonesia, Ethiopia, Nigeria, and Geneva, Switzerland.

XVII. LOGISTICS

Visa Requirements

List any specific Visa requirements or considerations for entry to countries that will be visited by consultant(s):

List recommended/required type of Visa for entry into counties where consultant(s) will work

Name of Country	Type of Visa		
Indonesia	☐ Tourist	☒ Business	☐ No preference
Ethiopia	☐ Tourist	☒ Business	☐ No preference
Nigeria	☐ Tourist	☒ Business	☐ No preference
	☐ Tourist	☐ Business	☐ No preference

Clearances & Other Requirements

Note: Most Evaluation/Analytic Teams arrange their own work space, often in their hotels. However, if Facility Access is preferred GH Pro can request it.

GH Pro does not provide Security Clearances, but can request **Facility Access**. Please note that Facility Access (FA) requests processed by USAID/GH (Washington, DC) can take 4-6 months to be granted. If you are in a Mission and the RSO can grant a temporary FA, this can expedite the process. If FA is granted through Washington, DC, the consultant must pick up his/her FA badge in person in Washington, DC, regardless of where the consultant resides or will work.

If **Electronic Country Clearance (eCC)** is required, the consultant is also required to complete the **High Threat Security Overseas Seminar (HTSOS)**. HTSOS is an interactive e-Learning (online) course designed to provide participants with threat and situational awareness training against criminal and terrorist attacks while working in high threat regions. There is a small fee required to register for this course. [Note: The course is not required for employees who have taken FACT training within the past five years or have taken HTSOS within the same calendar year.]

If eCC is required, and the consultant is expected to work in country more than 45 consecutive days, the consultant must complete the one week **Foreign Affairs Counter Threat (FACT) course** offered by FSI in West Virginia. This course provides participants with the knowledge and skills to better prepare themselves for living and working in critical and high threat overseas environments. Registration for this course is complicated by high demand (must register approximately 3-4 months in advance). Additionally, there will be the cost for one week's lodging and M&IE to take this course.

Check all that the consultant will need to perform this assignment, including USAID Facility Access, GH Pro workspace and travel (other than to and from post).

☐ USAID Facility Access (FA)

Specify who will require Facility Access: _____

☒ Electronic County Clearance (ECC) (International travelers only)

☒ High Threat Security Overseas Seminar (HTSOS) (required with ECC)

☐ Foreign Affairs Counter Threat (FACT) (for consultants working on country more than 45 consecutive days)

☒ GH Pro workspace

Specify who will require workspace at GH Pro: TPM and other Team Meetings

☒ Travel -other than posting (specify): Indonesia, Ethiopia, and Nigeria

☒ Other (specify): USAID/W communicate with Missions to be visited in advance, with request to Missions to assist with introductions to IP and MOH, as needed

XVIII. GH PRO ROLES AND RESPONSIBILITIES

GH Pro will coordinate and manage the evaluation/analytic team and provide quality assurance oversight, including:

- Review SOW and recommend revisions as needed
- Provide technical assistance on methodology, as needed
- Develop budget for analytic activity
- Recruit and hire the evaluation/analytic team, with USAID POC approval
- Arrange international travel and lodging for international consultants
- Request for country clearance and/or facility access (if needed)
- Review methods, workplan, analytic instruments, reports and other deliverables as part of the quality assurance oversight
- Report production - If the report is public, then coordination of draft and finalization steps, editing/formatting, 508ing required in addition to and submission to the DEC and posting on GH Pro website. If the report is internal, then copy editing/formatting for internal distribution.

XIX. USAID ROLES AND RESPONSIBILITIES

Below is the standard list of USAID's roles and responsibilities. Add other roles and responsibilities as appropriate.

USAID Roles and Responsibilities

USAID will provide overall technical leadership and direction for the analytic team throughout the assignment and will provide assistance with the following tasks:

Before Field Work

- SOW.
 - Develop SOW.
 - Peer Review SOW
 - Respond to queries about the SOW and/or the assignment at large.
- Consultant Conflict of Interest (COI). To avoid conflicts of interest or the appearance of a COI, review previous employers listed on the CV's for proposed consultants and provide additional information regarding potential COI with the project contractors evaluated/assessed and information regarding their affiliates.
- Documents. Identify and prioritize background materials for the consultants and provide them to GH Pro, preferably in electronic form, at least one week prior to the inception of the assignment.
- Local Consultants. Assist with identification of potential local consultants, including contact information.
- Site Visit Preparations. Provide a list of site visit locations, key contacts, and suggested length of visit for use in planning in-country travel and accurate estimation of country travel line items costs.
- Lodgings and Travel. Provide guidance on recommended secure hotels and methods of in-country travel (i.e., car rental companies and other means of transportation).

During Field Work

- Mission Point of Contact. Throughout the in-country work, ensure constant availability of the Point of Contact person and provide technical leadership and direction for the team's work.
- Meeting Space. Provide guidance on the team's selection of a meeting space for interviews and/or focus group discussions (i.e. USAID space if available, or other known office/hotel meeting space).
- Meeting Arrangements. Assist the team in arranging and coordinating meetings with stakeholders.
- Facilitate Contact with Implementing Partners. Introduce the analytic team to implementing partners and other stakeholders, and where applicable and appropriate prepare and send out an introduction letter for team's arrival and/or anticipated meetings.

After Field Work

- Timely Reviews. Provide timely review of draft/final reports and approval of deliverables.

XX. ANALYTIC REPORT

Provide any desired guidance or specifications for Final Report. (See [How-To Note: Preparing Evaluation Reports](#))

This report should describe the findings from the technical evaluation as well as findings related to the big picture and overarching issues. The report should separately and comprehensively address each of the objectives and questions listed in the SOW and the findings, interpretations, conclusions, and recommendations that should be clearly supported by the collected and analyzed data. Findings should be presented graphically where feasible and appropriate using graphs, tables, and charts. The final report should make recommendations for future action, including recommendations that may be relevant to PQM and for potential future projects in terms of both technical and managerial aspects. The report should ideally not exceed **approximately 40 pages in length** (not including appendices, list of contacts, etc.). The final report should contain an executive summary, table of contents, main text including findings, conclusions, and recommendations. Annexes should include the Scope of Work, description of the methodology used, lists of individuals and organizations consulted, data collection instruments (questionnaires, discussion guides, etc.) and bibliography of documents reviewed. The executive summary should accurately represent the report as a whole and should not exceed two pages.

The **Evaluation/Analytic Final Report** must follow USAID's Criteria to Ensure the Quality of the Evaluation Report (found in Appendix I of the [USAID Evaluation Policy](#)).

- a. The report must not exceed **40** pages (excluding executive summary, table of contents, acronym list and annexes).
- b. The structure of the report should follow the Evaluation Report template, including branding found [here](#) or [here](#).
- c. Draft reports must be provided electronically, in English, to GH Pro who will then submit it to USAID.
- d. For additional Guidance, please see the Evaluation Reports to the How-To Note on preparing Evaluation Draft Reports found [here](#).

Reporting Guidelines: The draft report should be a comprehensive analytical evidence-based evaluation/analytic report. It should detail and describe results, effects, constraints, and lessons learned, and provide recommendations and identify key questions for future consideration. The report shall follow USAID branding procedures. ***The report will be edited/formatted and made 508 compliant as required by USAID for public reports and will be posted to the USAID/DEC.***

The findings from the evaluation/analytic will be presented in a draft report at a full briefing with USAID and at a follow-up meeting with key stakeholders. The report should use the following format:

- Executive Summary: concisely state the most salient findings, conclusions, and recommendations (not more than 4 pages);
- Table of Contents (1 page);
- Acronyms
- Evaluation Purpose and Evaluation Questions (1-2 pages)
- Project [or Program] Background (1-3 pages)
- Evaluation Methods and Limitations (1-3 pages)
- Findings (organized by Evaluation Questions)

- Conclusions
- Recommendations
- Annexes
 - Annex I: Evaluation Statement of Work
 - Annex II: Evaluation Methods and Limitations
 - Annex III: Data Collection Instruments
 - Annex IV: Sources of Information
 - List of Persons Interviews
 - Bibliography of Documents Reviewed
 - Databases
 - [etc.]
 - Annex V: Statement of Differences (if applicable)
 - Annex VI: Disclosure of Any Conflicts of Interest
 - Annex VII: Summary information about evaluation team members, including qualifications, experience, and role on the team.

The evaluation methodology and report will be compliant with the [USAID Evaluation Policy](#) and [Checklist for Assessing USAID Evaluation Reports](#)

The Evaluation Report should **exclude** any **potentially procurement-sensitive information**. As needed, any procurement sensitive information or other sensitive but unclassified (SBU) information will be submitted in a memo to USIAD separate from the Evaluation Report.

All data instruments, data sets (if appropriate), presentations, meeting notes and report for this evaluation/analysis will be submitted electronically to the GH Pro Program Manager. All datasets developed as part of this evaluation will be submitted to GH Pro in an unlocked machine-readable format (CSV or XML). The datasets must not include any identifying or confidential information. The datasets must also be accompanied by a data dictionary that includes a codebook and any other information needed for others to use these data. Qualitative data included in this submission should not contain identifying or confidential information. Category of respondent is acceptable, but names, addresses and other confidential information that can easily lead to identifying the respondent should not be included in any quantitative or qualitative data submitted.

ANNEX II. DATA COLLECTION INSTRUMENTS

444 PQM Interim Evaluation

FINAL DRAFT – Survey to USAID Missions

Introduction: The Office of Health Systems (OHS) in USAID’s Bureau for Global Health has asked for an interim evaluation of the Promoting the Quality of Medicines project (PQM) to assess the effectiveness of the project’s technical approach, progress to date, and to determine if it addresses the needs of clients and the objectives of key health initiatives.

Through this survey, we are seeking input from all PQM field-based Activity Managers. We would like to ask you about your experience with and assessment of PQM’s work. We would also like to ask you about your thoughts about potential future directions for providing technical assistance to global initiatives concerned with access to quality pharmaceuticals and health system strengthening, in particular in light of the focus on the goal of universal health coverage. Even if you are no longer working with PQM, please complete this survey based on your recent experience with PQM.

We anticipate that no more than half an hour will be required to complete this survey.

Please complete the survey by **December 1, 2017**. If you have any questions, or are having trouble accessing the survey, please contact Randi Rumbold at rrumbold@ghpro.com.

Your participation in this evaluation is voluntary. You may refuse to answer any question in the survey or stop the survey at any time. And, of course, your answers are confidential.

Information on interviewee:

Q. How long have you been working with PQM in the country?

Less than 1 year
1~2 years
2~3 years
3~4 years
Longer than 5 years
No longer working with PQM

Q1

For which Mission are you responding? (For clarification of responses only. No individual country responses will be identified in the report.)

[Drop down menu]

Q2

What mission funding streams(s) for PQM are you representing? (check all that apply)
Maternal and Child Health

HIV/AIDS
 Family Planning/Reproductive Health
 Other Infectious Diseases
 Malaria
 Tuberculosis
 Other _____

Q3

PQM started in 2009. How many years has PQM been working in your country? _____ years

Q4

What were your key programmatic needs that led to the selection of PQM as your implementing partner? (check all that apply)

☐	Specific expertise in pharmaceutical quality assurance
☐	Emphasis on a system strengthening approach
☐	Capacity to work in both the public and private sectors
☐	Capacity to work at all levels of the health system
☐	Mission confidence in PQM technical staff
☐	MOH/DRA/DCQL request
☐	Ease of accessing the mechanism
☐	Other (please specify)

Q5a.

Overall, how satisfied are you with the ways in which PQM has been able to meet your technical programmatic needs?

	Not satisfied	Somewhat satisfied	Satisfied	Very satisfied	Extremely satisfied

Q5b. [COMMENT BOX]

Q6a.

Overall, how satisfied are you with how PQM has been able to meet your programmatic management needs?

–	Not satisfied	Somewhat satisfied	Satisfied	Very satisfied	Extremely satisfied

Q6b. [ADDITIONAL COMMENT BOX]

Q7

What are the most useful features of PQM as part of your Mission portfolio? (select no more than three)

Emphasis on sustainable improvements in quality assurance systems (consideration of various aspects of governance; human resources; information)
Engagement of government counterparts in the development of work plan activities
Leveraging world class expertise
Leveraging appropriate local or regional expertise
Flexibility of a cooperative agreement
Good project management skills of staff
Other (please specify)

Q8

Which of these PQM intermediate results areas are being addressed in your portfolio? (select all that apply)

IR 1. Medical product quality assurance systems strengthened
IR 2. Supply of quality-assured priority medicines increased
IR 3. Utilization of product quality information for regulatory decision making increased

Q9a.

How well do you feel that PQM is achieving their intended intermediate results?

–	Not well	Well	Very well	Don't know	N/A
IR 1. Medical product quality assurance systems strengthened					
IR 2. Supply of quality-assured priority medicines increased					
IR 3. Utilization of product quality information for regulatory decision making increased					

9b.

[Comment box: If applicable, can you provide an example when PQM has not performed well and why? If possible, please state the year/timeframe]

9c.

[Comment box: If applicable, can you provide an example when PQM has performed “well” and why? If possible, please state the year/timeframe]

9d.

[Comment box: If applicable, can you provide an example when PQM has performed “very well” and why? If possible, please state the year/timeframe]

Q10a

To what extent do you agree with the following statements regarding the quality of PQM work plans?

–	Do not agree (please comment below)	Agree somewhat (please comment below)	Strongly agree	N/A or don't know
PQM work plans provide clear justification and				

rationale for activities				
PQM activities are responsive to country needs				
PQM timelines are realistic				
PQM budgets are realistic				
PQM work plans are clearly written				
PQM work plans are useful for monitoring the project progress				
PQM work plans correspond to the Mission's PMP				
PQM activities are carried out as scheduled				
PQM's expected results are being achieved				

Q 10b.

[Comment box: If applicable, please provide an explanation of a comment(s) you do not agree with.]

Q 10c. [Comment box: If applicable, please provide an explanation of a comment(s) you agree somewhat with.]

Q11a.

How would you rate the technical and managerial quality of PQM staff at headquarters?

–	Very Poor	Poor	Good	Very Good	Excellent	DK/ N/A
Technical, overall						
PQM's technical backstopping (ex. Field visits)						
PQM's managerial capacity, overall						
PQM's responsiveness of field staff						
PQM's managerial support						

Q11b. Please explain an explanation for your ratings.

[COMMENT BOX]

Q12a.

If PQM has a field office, how would you rate the technical and managerial quality of PQM field staff?

–	Very Poor	Poor	Good	Very Good	Excellent	DK/NA
Technical						
Managerial						

Q12b. Please provide an explanation for your ratings.

[COMMENT BOX]

Q13a.

Please indicate your agreement with the following statements with respect to your communications with PQM/HQ?

–	Do not agree	Somewhat agree	Agree	NA
When I have a question or an issue, PQM always provides a timely response.				
PQM provides regular progress updates in response to my issues.				
My questions or issues are referred to an appropriate person when needed.				
Written communication from PQM is clear and free of major grammatical errors.				
PQM follows up to ensure that my questions/issues are addressed.				

Q13b. Please provide an explanation for your ratings.

[COMMENT BOX]

Q14a.

Overall, how effective is your communication with PQM/field office staff (ie., can you reach someone quickly; do you get a timely response?)

–	Do not agree	Somewhat agree	Agree	NA
When I have a question or an issue, PQM always provides a timely response.				
PQM provides regular progress updates in response to my issues.				

My questions or issues are referred to an appropriate person when needed.				
Written communication from PQM is clear and free of major grammatical errors.				
PQM follows up to ensure that my questions/issues are addressed.				

Q14b. Please provide an explanation for your ratings.

[COMMENT BOX]

Q15

Does PQM collaborate in a meaningful way with other USAID and USG projects/programs when appropriate?

Yes No NA DK

Q15b. Please provide an explanation for your ratings.

[COMMENT BOX]

Q16

Does PQM collaborate in a meaningful way with other donors relevant to the Mission's programmatic needs (e.g., World Bank, Global Fund, DFID, et al.) when appropriate?

Yes No NA DK

Q16b. Please provide an explanation for your ratings.

[COMMENT BOX]

Q17

Is there something that you think PQM should do to be more effective in its work? (specify)

Yes No NA DK

Q17b Please provide an explanation for your rating

[COMMENT BOX]

Q18

Do you think that PQM provides sufficient evidence of important outcomes regarding their work?

Yes No DK

Q18b Please provide an explanation for your rating.

[COMMENT BOX]

Q19

What is the most important evidence that PQM provides of its progress? (specify) or select [PQM does not provide evidence]

[COMMENT BOX]

Q20

What other kind of evidence would like PQM to provide? (specify)

[COMMENT BOX]

Q21

In your judgment, what would be the two most useful indicators of quality assurance system strengthening (as distinct from system performance, usually measured in terms of indicator such as a number of people trained)?

[COMMENT BOX]

Q22

Do you have further thoughts on PQM not captured above?

[COMMENT BOX]

Q23

Are there technical issues or concerns related to medicine quality assurance that PQM does not address that would be of interest to the Mission? If so, please briefly identify one or two of them and an explanation why these areas of are importance.

Area 1
Area 2

Thank you for participating!

444 PQM Midterm Evaluation

FINAL DRAFT – Survey to Manufacturers

Introduction: *The Office of Health Systems (OHS) in USAID’s Bureau for Global Health has asked for an interim evaluation of the Promoting the Quality of Medicines project (PQM) to assess the effectiveness of the project’s technical approach, progress to date, and to determine if it addresses the needs of clients and the objectives of key health initiatives.*

Through this survey, we would like to ask you about your experience with and assessment of PQM’s work.

Your participation in this evaluation is voluntary. You may refuse to answer any question in the survey or stop the survey at any time. And, of course, your answers are confidential.

If you have any questions or concerns regarding this survey, please contact the evaluation team at mmiralles137@gmail.com.

1. How did you first learn about the PQM project?

- a. Received a request for an expression of interest (EOI) from PQM
- b. Attended a meeting where PQM was introduced
- c. Heard about PQM from a colleague
- d. Read about PQM in the newspaper
- e. Other _____

2. Did you have any experience with USP before working with the PQM project team?

YES	NO	DK
-----	----	----

3. What is your objective in applying for technical assistance from PQM? (open ended)

COMMENT BOX

4. Are you still receiving technical assistance from PQM?

YES	NO	DK
-----	----	----

5. What type of technical assistance have you received from PQM? Check all that apply

- a. GMP
- b. Chemistry, manufacturing, controls
- c. Mock audit
- d. Support for WHO/ISO accreditation
- e. Dossier preparation/common technical document
- f. Dossier submission

6. What type of technical assistance do you still expect to receive from PQM? Check all that apply

- a. GMP
- b. Chemistry, manufacturing, controls
- c. Mock audit
- d. Dossier preparation/common technical document
- e. Dossier submission
- f. Assistance with corrective and preventative actions plans after Mock audit, and WHO PQ inspection.

7. In general, has the assistance you have received from PQM appropriate for your situation? (1 – 5 scale)

Not Appropriate	Somewhat appropriate	Appropriate
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7b. Please provide an explanation for your rating.

COMMENT BOX

8. How would you rate the quality of the technical assistance you have received from PQM?

Poor quality	Sometimes good, sometimes not so good	Always good quality	Very good quality	Excellent quality
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8b. Please provide an explanation for your rating.

COMMENT BOX

9. How would you rate the timeliness of the assistance you have received?

We always had to wait longer than expected until we received expected assistance	Sometimes there were delays with the assistance, but sometimes it was provided as scheduled	The assistance was always provided when it was scheduled
--	---	--

9b. Please provide an explanation for your comment.

COMMENT BOX

10. Overall, how would you rate your satisfaction with the technical assistance you have received from PQM

Very dissatisfied	Somewhat dissatisfied	Satisfied	Mostly satisfied	Very satisfied
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10b. Please provide an explanation for your rating.

COMMENT BOX

11. Do you have any advice for PQM for how to improve the assistance that they provide to manufacturers that want to produce quality-assured medicines? Please specify.

COMMENT BOX

Thank you for your participation!

444 PQM Midterm Evaluation

FINAL DRAFT – Guidelines for In-depth Interviews

Interviewee group – USAID Mission

Introduction: *The Office of Health Systems (OHS) in USAID’s Bureau for Global Health has asked for an interim evaluation of the Promoting the Quality of Medicines project (PQM) to assess the effectiveness of the project, progress to date, and to determine if it addresses the needs of clients and the objectives of key health initiatives.*

Through this interview, we would like to ask you about your experience with and assessment of PQM’s work. We would also like to ask you about your thoughts about potential future directions for providing technical assistance contributing to efforts to improve access to quality assured pharmaceuticals and health system strengthening, and particularly medicines regulatory capacity strengthening.

Your participation in this evaluation is voluntary. You may refuse to answer any question in the interview or stop the interview at any time. And, of course, your answers are confidential. Do we have your permission to begin?

Interviewee title:

Mission:

Funding sources for PQM (circle all that apply): malaria TB MNCH PRH HIV NTD

PQM working in-country since:

=====

1. What is the effectiveness of the project’s implementation?

- a. How well does PQM’s scope fit into the Mission’s overall PMP? Please explain.*
- b. Overall, how would you rate the effectiveness of PQM’s work in achieving the results that they described in their workplans?*
- c. Has PQM consistently met their targets with respect to outputs and outcomes?*
- d. What do you think they do particularly well?*
- e. Do you think that PQM does a good job of working with local counterparts in the NRA/NQCL/MOH? Please describe.*
- f. How about collaboration with other USAID implementing partners? Do they work well with them?*
- g. Do you think that having a field office has made a difference in the effectiveness of PQM’s technical assistance?*
- h. What issues, if any, have you had with PQM being able to meet their targets or achieve their desired outcomes? Please explain. Have they tried to address any of these issues?*

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FINAL DRAFT – Guidelines for In-depth Interviews

Interviewee group – DRA

Introduction: *The Office of Health Systems (OHS) in USAID’s Bureau for Global Health has asked for an interim evaluation of the Promoting the Quality of Medicines project (PQM) to assess the effectiveness of the project, progress to date, and to determine if it addresses the needs of clients and the objectives of key health initiatives.*

Through this interview, we would like to ask you about your experience with and assessment of PQM’s work. We would also like to ask you about your thoughts about potential future directions for providing technical assistance contributing to efforts to improve access to quality assured pharmaceuticals and health system strengthening, and particularly medicines regulatory capacity strengthening.

Your participation in this evaluation is voluntary. You may refuse to answer any question in the interview or stop the interview at any time. And, of course, your answers are confidential. Do we have your permission to begin?

Interviewee title:

Partner:

=====

I would like to begin by asking you to confirm the nature of your relationship with PQM. From reviewing PQM documents, and speaking with PQM staff and USAID, I understand that the relationship that your organization has with PQM is with respect to work on __ (summary) __. Is this correct? Have I missed anything?

=====

- 1. What is the effectiveness of the project’s implementation?**
 - a. What were the problems you were hoping PQM could help you to solve?*
 - b. What are the important outcomes (What are the results you care about)?*
 - c. Has there been a change in your priorities/objectives since working with PQM? If so, what changed?*
 - d. How effective has PQM been in addressing your priorities over time?*
 - e. What types of assistance has PQM provided over time?*
 - f. How effective is that assistance? Can you give examples of PQMs effectiveness?*

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FINAL DRAFT – Guidelines for In-depth Interviews

Interviewee group – Global and Regional Stakeholders

Introduction: *The Office of Health Systems (OHS) in USAID’s Bureau for Global Health has asked for an interim evaluation of the Promoting the Quality of Medicines project (PQM) to assess the effectiveness of the project, progress to date, and to determine if it addresses the needs of clients and the objectives of key health initiatives.*

Through this interview, we would like to ask you about your experience with and assessment of PQM’s work. We would also like to ask you about your thoughts about potential future directions for providing technical assistance to global initiatives concerned with access to quality assured pharmaceuticals, and health system strengthening, medicine regulatory capacity development.

Your participation in this evaluation is voluntary. You may refuse to answer any question in the interview or stop the interview at any time. And, of course, your answers are confidential. Do we have your permission to begin?

Interviewee title:

Global/Regional Stakeholder:

=====

I would like to begin by asking you to confirm the nature of your relationship with PQM. From reviewing PQM documents, and speaking with PQM staff and USAID, I understand that the relationship that your organization has with PQM is with respect to work on __ (summary) __. Is this correct? Have I missed anything?

With respect to this evaluation, I will be asking about PQM’s mandate to contribute to the global goal of increasing the supply of quality-assured medicines for public health priority conditions by advancing the medicines quality assurance agenda, including through advocacy, and providing technical leadership. Typically, PQM does this by participating in global and regional initiatives, engage in collaborative activities with other global entities, and develop state-of-the-art tools and methods to support the medicines quality assurance agenda.

=====

1. How well is PQM advancing the medicines quality assurance agenda and providing global technical leadership in medicines quality assurance?

- a. How well does PQM communicate what they are working on or what the program can offer?*
- b. How well does PQM meet its commitments to global/regional stakeholders? Please explain. Can you give me some examples?*
- c. What challenges, if any, have you experienced working with PQM? Please explain. Can you give me some examples?*

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FINAL DRAFT – Guidelines for In-depth Interviews

Interviewee group – USAID Health Element Teams

Introduction: *The Office of Health Systems (OHS) in USAID’s Bureau for Global Health has asked for an interim evaluation of the Promoting the Quality of Medicines project (PQM) to assess the effectiveness of the project, progress to date, and to determine if it addresses the needs of clients and the objectives of key health initiatives.*

Through this interview, we would like to ask you about your experience with and assessment of PQM’s work. We would also like to ask you about your thoughts about potential future directions for providing technical assistance contributing to efforts to improve access to quality assured pharmaceuticals and health system strengthening, and particularly medicines regulatory capacity strengthening.

Your participation in this evaluation is voluntary. You may refuse to answer any question in the interview or stop the interview at any time. And, of course, your answers are confidential. Do we have your permission to begin?

Interviewee title:

Core/Health Element: *malaria TB MNCH FPRH HIV NTD OHS*

=====

I would like to begin by asking you to confirm the nature of your relationship with PQM. From reviewing PQM documents, and speaking with PQM staff and the AOR team, I understand that the relationship that your organization has with PQM is with respect to work on __ (summary) __. Is this correct? Have I missed anything?

Overall Evaluation Question: What is the effectiveness of the project’s implementation of USAID Washington funded work? (directed core funds).

1. Related to PQMs work, how effective has PQM been in helping you achieve your objectives?

- a. What were the issues you were hoping PQM could help you to solve?*
- b. What are the important outcomes or results from PQM’s work that you care the most about?*
- c. Has there been a change in your priorities for PQM over time? If so, what are they?*
- d. How effective has PQM been in addressing your priorities over time?*
- e. What factors contributed to their effectiveness? Prompt: capacity, timeliness, management...*
- f. Have you had any challenges working with PQM with respect to making progress toward meeting your objectives? What are those challenges? Prompt: poor planning, lack of technical capacity, poor communications, nonresponsiveness. Can you describe what happened?*

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FINAL DRAFT – Guidelines for In-depth Interviews

Interviewee group – Manufacturers

Introduction: *The Office of Health Systems (OHS) in USAID's Bureau for Global Health has asked for an interim evaluation of the Promoting the Quality of Medicines project (PQM) to assess the effectiveness of the project, progress to date, and to determine if it addresses the needs of clients and the objectives of key health initiatives.*

Through this interview, we would like to ask you about your experience with and assessment of PQM's work. We would also like to ask you about your thoughts about potential future directions for providing technical assistance contributing to efforts to improve access to quality assured pharmaceuticals and health system strengthening, and particularly medicines regulatory capacity strengthening.

Your participation in this evaluation is voluntary. You may refuse to answer any question in the interview or stop the interview at any time. And, of course, your answers are confidential. Do we have your permission to begin?

Interviewee title:

Partner:

=====

I would like to begin by asking you to confirm the nature of your relationship with PQM. From reviewing PQM documents, and speaking with PQM staff and USAID, I understand that the relationship that your organization has with PQM is with respect to work on __ (summary) __. Is this correct? Have I missed anything?

=====

Background information:

1. *How did you learn about PQM?*
2. *What is your objective in obtaining assistance from PQM?*
3. *What type of technical assistance did you receive? (Select all that apply. If it is not included here, please specify.)*

- 1) *Product formulation*

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FINAL DRAFT – Guidelines for In-depth Interviews

Interviewee group – PQM Staff

Focus question: How have PQM’s management structure, processes, and staffing patterns helped or hindered progress towards achieving the project’s goal and results?

Interviewee title:

Structure

1. Can you describe your management structure? How has it changed over time?
2. What do you think are the advantages of this new structure?
3. PQM recently started to open field offices. Can you explain the rationale for where and when to open field offices?
4. What have been your challenges in setting up field offices?

Workplan development

1. Can you describe the work plan development process? Is it the same for core work plans as for mission-funded work plans?
2. How does PQM ensure that the technical quality of the work plans?
3. Who is responsible for tracking work plan development? What tools are used to support this?
4. Does PQM track how long it takes to get USAID approval for work plans (mission and GH)? How long on average does it take to draft a work plan, and how long does it take to get it approved? Do you have any concerns about work plan development or about obtaining work plan approvals?
5. Would you say that PQM work plans are usually realistic?

Work plan implementation

1. Do you track implementation? What tools do you use to do this?
2. What are your greatest challenges with implementation?

HR

1. How much of a challenge has it been for PQM to recruit qualified staff? Describe.
2. Can you describe your recruitment process?
3. Once you have identified someone, how long does the on-boarding process take?
4. How about staff retention? Is staff retention a concern? Please describe.
5. To what extent does PQM rely on short term consultants? Who is responsible for identifying short term consultants? What challenges, if any, do you face with respect to identifying and recruiting short term consultants?

Finance

1. We have received a copy of your funding profile. Can you describe how you develop it and how it is used?
2. How are work plan budgets developed? Who is responsible for developing the work plans?

ANNEX III. SOURCES OF INFORMATION

A. Documents provided by PQM

OVERVIEW	
Documents for Evaluation Team	• PQM External Evaluation Briefing Book • Overview PPT for the Evaluation Team
Organograms	• PQM Organogram • Field Office Organogram • Support Functions Organogram • Functional Relationships
Agreement Documents	• PQM Cooperative Agreement, 2009 • PQM Extension Request, 2013 • PQM Extension Letter, September 23, 2013 • PQM Modifications (#1-#30)
TECHNICAL DOCUMENTS	
Technical Briefs	• Increasing the Supply of Anti-TB Medicines through Market Shaping Approaches: The Case of Kanamycin (<i>Note: Also included under Core TB</i>) • Promoting Public Safety through Building a Sustainable QA/QC System for Medicines in Ethiopia (<i>Note: Also included under Ethiopia</i>) • Building Local Capacity to Increase Supply of Quality-Assured Medicines for Priority Health Programs Ethiopia (<i>Note: Also included under Ethiopia</i>) • Improving Access to Quality-Assured Medicines through an efficient Medicines Registration System in Ethiopia • Protecting the Public: Strengthening Indonesia's Pharmaceutical Post-Marketing Surveillance Capacity to Ensure Quality-Assured Medicines for All
Technical Strategies & Guidelines	• A Framework for Risk-Based Resource Allocation for Pharmaceutical Quality Assurance for Medicines Regulatory Authorities in Low- and Middle-Income Countries (<i>Note: Also included under Cross Bureau</i>) • Guidance for Implementing Risk-based Post-marketing Quality Surveillance in Low- and Middle-income Countries (<i>Note: Also included under Cross Bureau</i>) • Strengthening Manufacturing Capacity to Improve Access to Quality-Assured Essential Medicines • Improving the Quality of Medicines in Low- and Middle-Income Countries by Strengthening National Quality Control Laboratories • Analytical Instrumentation Support Program (AISP) for Low- and Middle- Income Countries • Strengthening the Quality Assurance and Regulatory Systems for Medical Products in Low- and Middle-Income Countries (Advance Draft) • PQM Good Manufacturing Practices Technical Assistance Overview

Technical Tools, Templates, Calculators & Job Aids	• Interlaboratory Comparison Tool • Integrated Regulatory Assessment Tool (IRAT) • Stepwise Assessment Tool towards Accreditation (SATTA) • Laboratory Capability Maturity Model (LCMM) • Tool for Initial Evaluation and Selection of Pharmaceutical Manufacturers for Technical Assistance • Risk-Based GMP Assessment and Benchmarking Tool • Medicines Risk-based Surveillance (MedRS) Tool • Laboratory Equipment Troubleshooting Tool and Common Maintenance Guidance • Instrumentation Master List • Mobile Phase and Solutions Preparation Labels • Sample Receiving Labels • Logbook Template • Analytical HPLC Problem Prevention • USP Performance Verification Test and Extended Release Calculations • Dissolution Extended Release Profile • Assay, Impurity, and Uniformity of Dosage Unit Calculation Tool • LOD and LOQ Calculation Tool • Disposal of Chemical Waste Form • HPLC & GC Column Tracking
Additional Technical Materials	• Three- Level Approach for Quality Control of Medicines • Survey of the quality of selected antimalarial medicines circulating in six countries of sub-Saharan Africa (USP contributed FY11) • PQM Technical Leadership on Normative Guidance • List of Select Confidential Assessment Reports
COMMUNICATION MATERIALS	
Factsheet	• PQM Factsheet • PQM Approach Factsheet • PQM GMP Brochure • Screening Medicines with the GPHF-Minilab Fact Sheet • PQM Support for Regional Medicines Regulatory Harmonization and Reliance in Africa
Success Stories	• PPB Expands Medicines Quality Surveillance in Kenya (2014-2015) • Best Practices Building the Capacity of Local Manufacturers to increase the Supply of Quality-Assured MNCH Essential Medicines • Protecting Newborns by Expanding Locally Manufactured Quality-Assured Medicines (2017) • Strengthening Burma's Capacity to Test for Quality Medicines (2017) • Reducing the Risk of HIV Transmission in Ethiopia (2017) • Building Local Laboratory Capacity to Improve Health Outcomes (2017) • Why Lab Accreditation Matters for Public Health (2017)

	• Securing Liberia's Borders to Protect Medicine Quality • Applying a Collaborative Learning Model to Sustainably Build Staff Capacity: Experiences from Nigeria, Burma, and Kazakhstan (2017) • Protecting Patients from Poor-Quality Medicines by Boosting Laboratory Capacity – Nigeria (2017) • Building Sustainable Global Health Systems: Local Ownership of Lab Instruments/Equipment Maintenance in Ethiopia (2016) • Peru Strengthens its Medicine Quality Control Approach (2015) • Reducing quality assurance costs by building Ethiopia's capacity to calibrate laboratory instrumentation • Nigeria Builds Capacity for Data-Driven Decision-Making in Medicines Quality Assurance • Strengthening Quality Assurance Systems for Antimalarials in Nigeria
Media	• Falsified medicine — tackling a serious threat to public health. Devex: July 20, 2017 • Generation next: Ensuring quality medicines for newborns. Devex: July 13, 2017 • Increasing the sources of quality medicines in LMICs: Challenges and Strategies. Devex: July 6, 2017 • Poor-quality medicine: A global pandemic. Devex: June 29, 2017
JOURNAL ARTICLES	
N/A	• Anyakora Chimezie, 2017. Cost benefit of investment on quality in pharmaceutical manufacturing: WHO GMP pre- and post-certification of a Nigerian pharmaceutical manufacturer • JaCinta Batson et al, 2016. Assessment of the effectiveness of the CD3+ tool to detect counterfeit and substandard anti-malarials. Malaria Journal 15:119. • Mustapha Hajjou et al, 2015. Monitoring the Quality of Medicines: Results from Africa, Asia, and South America. The American Journal of Tropical Medicine and Hygiene 92 (6): 68-74. • Mustapha Hajjou and Patrick Lukulay, 2014. Potential use of handheld Raman devices as tools for screening medicines for quality. BioPharma Asia 2 (1): 14-21. (available in DEC) • Victor Pribluda et al, 2014. The Three-Level Approach: A Framework for Ensuring Medicines Quality in Limited-Resource Countries. Pharmaceutical Regulatory Affairs Journal 3 (117). • Laura Krech et al, 2014. Cambodian Ministry of Health Takes Decisive Actions in the Fight against Substandard and Counterfeit Medicines. Tropical Medicine and Surgery 2 (2). • Victor Pribluda et al, 2014. Were medicine quality and pharmaceutical management contributing factors in diminishing artemisinin efficacy in Guyana and Suriname? Malaria Journal 13:77. • Souly Phanouvong et al., 2013. The Quality of Antimalarial Medicines in Western Cambodia: A Case Study Along the Thai-Cambodian Border. Southeast Asian Journal of Tropical Medicine and Public Health 4 (33): 363-373. • Souly Phanouvong et al, 2013. The Quality of Antimalarial Medicines in Eastern Thailand: A Case Study Along the Thai-Cambodian Border. Southeast Asian Journal of Tropical Medicine and Public Health 4 (33): 349-362. • Lawrence Evans et al, 2012. Quality of anti-malarials collected in the private and informal sectors in Guyana and Suriname. Malaria Journal 11:203. • Mustapha Hajjou et al, 2012. Assessment of the performance of a handheld Raman device for potential use as a screening tool in evaluating medicines quality. Journal of Pharmaceutical and Biomedical Analysis 74 (1): 47-55 • Victor Pribluda et al, 2012. Implementation of basic quality control tests for malaria medicines in Amazon Basin countries: results

	for the 2005–2010 periods. Malaria Journal 11:202. • Souly Phanouvong, Malaria 2012: Saving Lives in the Asia-Pacific • Hari Ramanathan et al, 2017. Role of USP Interlaboratory Comparison Testing Program in Strengthening Official Medicines Control Laboratories in Low- and Middle-Income Countries (Not published)
PRESENTATIONS AND POSTERS	
N/A	Conference Posters • The Medicines Quality Database (MQDB): Successfully Sharing Information about Poor Quality Medicines for Infectious Diseases in Asian Countries (2014) • Ensuring the quality of medicines in the Greater Mekong Sub-region to protect the public health (2012) • Three-Level Approach: A Risk-Based, Cost-Effective Approach to Medicines Quality Monitoring in Low-and Middle-Resource Countries (2011) • USP Promoting the Quality of Medicines Program (PQM) Activities in Southeast Asia (2010-2011) • Three-Level Approach for Ensuring the Quality of Medicines in Resource-Limited Countries (2010) • Medicine Quality Monitoring in Cambodia-Poster (2009) Conferences/Workshops • Union Conference: Strengthening quality assurance systems of pharmaceutical manufacturers to endure availability of affordable TB medicines on the global market • Consultative Workshop on Building Sustainable Medicines Regulations through Risk-Based Quality Assurance and Improved Regulatory Information Management (Bangkok Workshop)
KNOWLEDGE MANAGEMENT	
N/A	• Knowledge Management Strategy • Knowledge Management Workplan
MANAGEMENT TOOLS	
N/A	• Newdea Summary • Newdea Non-Profit Organization-- company informational sheet • Newdea Product Sheet • Portfolio Review Program Scorecard template • Project Charter template • RACI template • Risk Register template • Issues Log template

MONITORING AND EVALUATION	
N/A	• PQM Monitoring and Evaluation Plan • List of program indicators • Results Framework • Performance Indicator Reference Sheets (PIRS)
WORK PLAN GUIDANCE	
N/A	• PQM FY18 Work Plan Template • PQM FY18 Work Plan Development Checklist • PQM FY18 Work Plan Priorities Table • PQM FY18 Problem Analysis Workshop Slides • PQM FY18 Work Plan Development Agenda (June 2017) • Guidance for PQM FY18 Work Plan Reviews • PQM FY18 Work Plan Development Tracking Tool
ANNUAL AND QUARTERLY REPORTS	
PQM Annual Performance Reports	• Promoting the Quality of Medicines Program Annual Report: Project Year 2016: October 1, 2015-September 30, 2016 • Promoting the Quality of Medicines Program Annual Report: Project Year 2015: October 1, 2014-September 30, 2015 • Promoting the Quality of Medicines Program Annual Report: Project Year 2014: October 1, 2013-September 30, 2014 • Promoting the Quality of Medicines Program Annual Report: Project Year 2013: October 1, 2012-September 30, 2013 • Promoting the Quality of Medicines Program Annual Report: Project Year 2012: October 1, 2011-September 30, 2012 • Promoting the Quality of Medicines Program Annual Report: Project Year 2011: October 1, 2010-September 30, 2011 • Promoting the Quality of Medicines Program Annual Report: Project Year 2010: October 1, 2009-September 30, 2010
PQM Quarterly Reports	• Promoting the Quality of Medicines Program Quarterly Report: Project Year 2017, Quarter 3: April - June 2017 • Promoting the Quality of Medicines Program Quarterly Report: Project Year 2017, Quarter 2: January - March 2017 • Promoting the Quality of Medicines Program Quarterly Report: Project Year 2017, Quarter 1: October - December 2016 • Promoting the Quality of Medicines Program Quarterly Report: Project Year 2016, Quarter 4: July - September 2016 • Promoting the Quality of Medicines Program Quarterly Report: Project Year 2016, Quarter 3: April – June 2016 • Promoting the Quality of Medicines Program Quarterly Report: Project Year 2016, Quarter 2: January – March 2016 • Promoting the Quality of Medicines Program Quarterly Report: Project Year 2016, Quarter 1: October – December 2015 • Promoting the Quality of Medicines Program Quarterly Report: Project Year 2015, Quarter 4: July – September 2015 • Promoting the Quality of Medicines Program Quarterly Report: Project Year 2015, Quarter 3: April – June 2015 • Promoting the Quality of Medicines Program Quarterly Report: Project Year 2015, Quarter 2: January – March 2015 • Promoting the Quality of Medicines Program Quarterly Report: Project Year 2015, Quarter 1: October – December 2014 • Promoting the Quality of Medicines Program Quarterly Report: Project Year 2014, Quarter 4: July – September 2014 • Promoting the Quality of Medicines Program Quarterly Report: Project Year 2014, Quarter 3: April – June 2014 • Promoting the Quality of Medicines Program Quarterly Report: Project Year 2014, Quarter 2: January – March 2014 • Promoting the Quality of Medicines Program Quarterly Report: Project Year 2014, Quarter 1: October – December 2013

	- Promoting the Quality of Medicines Program Quarterly Report: Project Year 2013, Quarter 4: July – September 2013 - Promoting the Quality of Medicines Program Quarterly Report: Project Year 2013, Quarter 3: April – June 2013 - Promoting the Quality of Medicines Program Quarterly Report: Project Year 2013, Quarter 2: January – March 2013 - Promoting the Quality of Medicines Program Quarterly Report: Project Year 2013, Quarter 1: October – December 2012 - Promoting the Quality of Medicines Program Quarterly Report: Project Year 2012, Quarter 4: July – September 2012 - Promoting the Quality of Medicines Program Quarterly Report: Project Year 2012, Quarter 3: April – June 2012 - Promoting the Quality of Medicines Program Quarterly Report: Project Year 2012, Quarter 2: January – March 2012 - Promoting the Quality of Medicines Program Quarterly Report: Project Year 2012, Quarter 1: October 2011 – December 2011 - Promoting the Quality of Medicines Program Quarterly Report: Project Year 2011, Quarter 4: July – September 2011 - Promoting the Quality of Medicines Program Quarterly Report: Project Year 2011, Quarter 3: April – June 2011 - Promoting the Quality of Medicines Program Quarterly Report: Project Year 2011, Quarter 2: January – March 2011 - Promoting the Quality of Medicines Program Quarterly Report: Project Year 2011, Quarter 1: October – December 2010 - Promoting the Quality of Medicines Program Quarterly Report: Project Year 2010, Quarter 4: July – September 2010 - Promoting the Quality of Medicines Program Quarterly Report: Project Year 2010, Quarter 3: April – June 2010 - Promoting the Quality of Medicines Program Quarterly Report: Project Year 2010, Quarter 2: January – March 2010 - Promoting the Quality of Medicines Program Quarterly Report: Project Year 2010, Quarter 1: October – December 2009
FINANCIAL DOCUMENTS	
N/A	PQM Funding and Ceiling Profile
AFRICA AND MIDDLE EAST	
Angola	- Monitoring & Evaluation Plan - Work Plans
Benin	- Country Overview - Monitoring & Evaluation Plan Documents - PMS (Post Marketing Surveillance) Presentation (French) - Strengthening the Capacity of Benin National Medicine Quality Control Laboratory: Training in Good Documentation Practices and Dissolution (Trip Report FY16) - Training in Sampling and Screening of Antimalarial Medicines, Collecting and Screening a Set of Samples, and Review of Lab Equipment (Trip Report FY15) - MQDB report (French FY16) - Strengthening the Capacity of Benin National Medicine Quality Control Laboratory: Training in Good Laboratory Practice and Fourier Transform Infrared Spectroscopy (Trip Report FY10) - Work Plans

Burkina Faso	- Country Overview - Monitoring & Evaluation Plan Documents - Initial Assessment of Medicines QA/QC Capability (Trip Report FY15) - Workshop Training on Basic Laboratory Concepts and Technical Evaluation of National Quality Control Laboratory Equipment (Trip Report FY15) - Training in Sampling and Screening of Antimalarial Medicines, and Survey of Antimalarials Quality (FY16) - Work Plans
Ethiopia	- Country Overview - Monitoring & Evaluation Plan - Work Plans Documents <i>PQM Supported EFMHACA Documents</i> - Directives and Guidelines (13 documents) - Strategies and Roadmaps (2 documents) <i>Link between PQM activities and USAID priorities</i> - Link between PQM activities and USAID priorities <i>Manufacturers</i> - Manual for Good Manufacturing Practice (GMP) Inspections (FY15) <i>PMS Report</i> - Post-Marketing Quality Surveillance of Antimalarial Medicines Report (FY13) - PMS report on ARV and OI medicines circulating in Ethiopia (FY12) - PMS report on ARV and OI medicines circulating in Ethiopia (2nd round FY14) - Post-Marketing Quality Surveillance of MCH medicines circulating in Ethiopia (First round FY15) - Post-Marketing Quality Surveillance of Antimalarial Medicines FY16) <i>Presentations</i> - US Ambassador of Ethiopia PQM visit (FY17) <i>Regulatory assessments</i> - Assessment of the Tigray Regional Food, Medicine, and Healthcare Administration and Control Core Process (FY14) - Assessment the Addis Ababa Food, Medicine, and Healthcare Administration and Control Authority (FY14) - Assessment of the Amhara Regional State Food, Medicine, and Healthcare Administration and Control in Ethiopia (FY14) - Assessment of the Quality Control and Regulation Core - Process of Oromia Health and Health-Related Services and Products (FY14) Draft form

	• Assessment of the Afar Regional Health and Health Related Products and Services Quality Control process (FY16) • Assessment of the Benishangul-Gumuz Regional Health and Health Related Products and Services Quality Control process (FY16) • Assessment of the Somali Regional Health and Health Related Products & Services Quality Control Agency (FY16) Regulatory Workforce Development • QMS module (FY17) • Modular curriculum for Master of Science Degree in Regulatory Affairs (FY15) Technical Briefs • Promoting Public Safety through Building a Sustainable QA/QC System for Medicines in Ethiopia • Building Local Capacity to Increase Supply of Quality-Assured Medicines for Priority Health Programs Ethiopia
Ghana	• Country Overview • Monitoring & Evaluation Plan • Work Plans Documents • FDA Certificate of Accreditation (FY15) • Promoting the Quality of Medicines (PQM) Program Ghana Performance Report (Annual Report FY16) • Strengthening the Quality of Medicines (Annual Report FY12) • Strengthening the Quality of Medicines (Annual Report FY14) • Strengthening Quality Systems (Annual Report FY15) • Waste Management Presentation (FY15)
Guinea	• Country Overview • Monitoring & Evaluation Plan • Work Plans Documents • Launching Medicines Quality Monitoring in Conakry (Trip Report FY16) • Review of the Pharmaceutical Law Documents and Launch of the Establishment of Post-Marketing Surveillance (Trip Report FY16) • Revision of Guinea's Pharmaceutical Law and Assessment of DNPL's Registration Department (Trip Report FY17)
Kenya	• Country Overview • Monitoring & Evaluation Plan • Work Plans Documents: • Monitoring the Quality of Antimalarial Medicines Circulating Report (FY11) • Monitoring the Quality of Antimalarial Medicines Circulating Report (FY12) • Monitoring the Quality of Antimalarial Medicines Circulating Report (FY13) • Antimalarial Medicines Quality Monitoring Program Report (FY14)

	- Monitoring the Quality of Antimalarial Medicines Circulating Report (FY15) - Protocol for Post-Marketing Surveillance of Antimalarials
Liberia	- Country Overview - Monitoring & Evaluation Plan - Work Plans Documents: - Conduct Medicine Quality Monitoring at Sentinel Sites in Liberia and Meet with the Liberia Medicines and Health Products Regulatory Authority (Trip Report FY13) - Medicines Quality Monitoring Program Dissemination Meeting (Trip Report FY16) - Sustaining Medicines Quality Control Training in Resource-Limited Countries: The Visiting Scientists Program
Madagascar	- Sample Test Report (FY12) - Work Plans
Mali	Country Overview Monitoring & Evaluation Plan Work Plans Documents: - Minilab Dissemination Workshop (French Presentation FY15) - Minilab Supervisory Visit Report (French FY14) - Revised Ministerial Decree (French FY11) - Dissemination of MQM Report (French Presentation) - MQM Report (FY13) - Strengthening Quality Systems and Refresher Training on High Performance Liquid Chromatography and Fourier Transform Infrared Spectroscopy (Trip Report FY11) - Training on Good Documentation Practices and UV-Visible Spectrophotometry and Facilitation of Medicines Quality Monitoring Activities (Trip Report FY14)
Mozambique	- Country Overview - Monitoring & Evaluation Plan - Work Plans Documents - Training on Performance Verification Test, Dissolution, and Karl Fischer Titration (Trip Report FY12) - Laboratory training for LNCQM staff (Trip Report Fy 13) - Medicine Quality Database (FY13)

Nigeria	• Country Overview • Monitoring & Evaluation Plan • Work Plans Documents Curriculum Support • Quality Assurance Curriculum Review Workshop (FY16) PMS Report • Protocol for Malaria Medicine Quality Monitoring (FY16) • Quality Assessment of Oxytocin, Misoprostol, Calcium Gluconate and Magnesium Sulphate at different levels of supply chain (FY17) • Medicine Quality Monitoring of Antimalarial Medicines Circulating (FY15) • Medicine Quality Monitoring Survey (FY17) QC Lab • Agulu Gap Assessment (FY15) • Kaduna Gap Assessment (FY15) QAPolicy • National Quality Assurance Policy For Medicines and Other Health Products (FY15) Regulatory Actions • Mop Up of Poorly Stored Oxytocin (June 2017) • Mop Up of Poorly Stored Oxytocin (Aug/Sept 2017) • Mop Up of Poorly Stored Oxytocin (July 2017)
Rwanda	• Work Plans Documents • Assessment of Medicine Quality Assurance (FY09)
Senegal	• Country Overview • Monitoring & Evaluation Plan • Work Plans Documents • Continued Strengthening of the National Quality Control Laboratory (Trip Report FY 16) • Educative Communication Campaign on Combating Counterfeit Medicines on the Illicit Market in Senegal (Trip Report FY11) • Inter-Ministerial Workshop on Reinforcing Regulatory Actions Against Counterfeit and Substandard Medicines and Illicit Markets (FY15) • MQM Report (French FY09) • MQM Report (French FY10)

	• MQM Report (French FY 12)
West Bank	• Country Overview • Monitoring & Evaluation Plan • Work Plans Documents Baseline Good Manufacturing Practices (GMP) Assessment of the Pharmaceutical Manufacturers (FY 15)
ASIA	
Bangladesh	• Country Overview • Monitoring & Evaluation Plan • Work Plans Documents • Gap Analysis to Determine Needs for Capacity Strengthening of Medicines Regulatory, Quality Assurance, and Quality Control Systems (FY16) • Gap Analysis to Determine Needs for Capacity Strengthening of the National Drug Control Laboratory (FY16)
Burma	• Country Overview • Monitoring & Evaluation Plan • Work Plans Documents • Mechanical and Analytical Calibration of HPLC and Dissolution Tester for Proper Operations to Analyze Samples of Pharmaceuticals with Reliable Results in Support of Laboratory Functions of the Burma/Myanmar Department of Food and Drug Administration (Technical Report FY14) • Mechanical and Analytical Calibration of UPLC/HPLC and Dissolution Tester in Support of Laboratory Functions of the Burma/Myanmar Department of Food and Drug Administration (Technical Report FY15) • Training on Titrimetry (Trip Report FY17) • Technical Assistance on Laboratory Design to DFDA Nay Pyi Taw and Mandalay Laboratories (Trip Report)
Cambodia	• Country Overview • Work Plans Documents • Cambodia Historical PMS data • USAID Supports Seizure of Illegal Medicines in Cambodia (Memo FY13)

Indonesia	• Country Overview • Monitoring & Evaluation Plan • Work Plans Documents • Central BPOM/BINFAR Officers to Participate in WHO PQ Activities at Manufacturers (FY15) • Supply Chain Management Monitoring for ARV Decentralization (FY15) • Capacity Building in the Use of HPLC and Dissolution Testing to Detect Counterfeit and Sub-standard Medicines (FY16) • Quality Control Laboratory Training for Indonesian Pharmaceutical Manufacturers (FY16) • Capacity Building of the Quality Control Laboratory on Analytical Testing of HIV Medicines in Jayapura and Jakarta (FY16)
Pakistan	• Country Overview • Monitoring & Evaluation Plan • Work Plans Documents • PQM Initial Assessment of Medicines Regulatory, Quality Assurance, and Quality Control Systems to Determine Gaps for Capacity Building (Trip Report FY15) • Integrated regulatory Information Management System for Medicines Regulatory Authorities (FY16) • Technical Assistance to Pakistani Manufacturers Expands Quality-Assured Chlorhexidine for Newborns (Memo FY17)
Philippines	• Country Overview • Monitoring & Evaluation Plan Documents • FDA Advisory No. 015 (FY16) • FDA Advisory No.100 (FY16) • Training Workshop on Good Distribution and Storage Practices (GDSP) for Philippines Regulatory Authority (Trip Report FY17) • Medicine Quality Monitoring Program (FY17) • CALABARZON DOTS Facility Inspection and Sample Collection (FY17) • PMS Historical Data • Workshop on Risk-Based Post Market Surveillance (PMS) Guideline in Philippines (Trip Report FY17)
RDMA	• Country Overview • Work Plans Documents • BREMERE Initiative Workshop (FY15)

EASTERN EUROPE AND CENTRAL ASIA	
Kazakhstan	• Country Overview • Monitoring & Evaluation Plan • Documents • Laboratory Information File • Work Plans
Uzbekistan	• Country Overview • Monitoring & Evaluation Plan • Work Plans Documents • Confidential reports: cross reference
LATIN AMERICA AND CARIBBEAN	
AMI	• Work Plans Documents • MedvigiLI: Supporting Visual Inspection of Medicines in the Field (FY17) • MedvigiLI (Presentation FY17) • MQM Historical Data (2009-2011) • Protocol Development for Medicine Quality Monitoring (2011) • -Sustainable South-South Collaboration Workshop • Three-Level Approach for Quality Control of Medicines (Presentation) • Three-Level Approach in AMI (Spanish Presentation 2011) • Executive Summary: Quality of Antimalarial Medicine in Facilities from the Private and Informal Sector in Colombia (FY13) • Quality of antimalarials in the private and informal sector in the municipalities of Colombia (Spanish version FY17)
Guatemala	• Work Plans Technical Documents • Maternal and Child Health Study (FY12) • Study on the Quality of Emergency Obstetric Medicines (Spanish FY12)

N/A	
Cross Bureau	• Program Overview • Monitoring & Evaluation Plan • Quarterly Progress Tables • Work Plans Documents • A Framework for Risk-Based Resource Allocation for Pharmaceutical Quality Assurance for Medicines Regulatory Authorities in Low and Middle-Income Countries (FY17) • Guidance for Implementing Risk-based Post-marketing Quality Surveillance in Low and Middle-income Countries (FY17) COB 10/9 • -Assessment of the effectiveness of the CD3+ tool to detect counterfeit and substandard anti-malarials (Presentation FY16) • Expert Consultation on Risk-based Post-Marketing Medicines Quality Surveillance for Low and Middle-Income Countries (LMICs) (Presentations FY16) • Post Marketing Surveillance of Medicines (Presentations FY16) • The Importance of Drug Quality: Setting the Scene (Presentations FY5) • Assessment of a Portable Raman Device for Use as a Tool to Screen Medicines for Quality (Presentations FY13) • Surveillance of Pharmaceutical Product Quality and Safety (Presentations FY12) • 5-Year Overview of Strengthening Regional Capacity in Medicines Quality in the Mekong Subregion: A Focus on Counterfeit and Substandard Medicines (Presentations FY10) • Strengthening Developing Countries to Detect Counterfeit and Substandard Medicines (Presentations FY10)
Core Malaria	• Program Overview • Monitoring & Evaluation Plan • Quarterly Progress Tables • Work Plans Documents • Benin Antimalarial Medicines Monitoring Study (FY13) • Congo Antimalarial Medicines Monitoring Study (FY13) • Liberia Antimalarial Medicines Monitoring Study (FY13) • Uganda Antimalarial Medicines Monitoring Study (FY13) • Ghana Antimalarial Medicines Monitoring Study (FY 14) • Nigeria Antimalarial Medicines Monitoring Study (FY14) • Cameroon Antimalarial Medicines Monitoring Study (FY15) • Congo Antimalarial Medicines Monitoring Study (FY15) • Malawi Antimalarial Medicines Monitoring Study (FY15) • Tanzania Antimalarial Medicines Monitoring Study (FY15) • Benin Antimalarial Medicines Monitoring Study (FY16)

	• Malawi Antimalarial Medicines Monitoring Study (FY16) • Nigeria Antimalarial Medicines Monitoring Study (FY16) • Survey of the Quality of Selected Antimalarial Medicines Circulating in Madagascar, Senegal, and Uganda (DQI 2009) • Screening Methods: • Minilab Supplement 2016 • Artesunate • Artemether • Minilab Supplement 2013 • Lumefantrine
Core MNCH	• Program Overview • Monitoring & Evaluation Plan • Quarterly Progress Tables • Work Plans Documents • Kenya Regional Workshop on Advanced Good Manufacturing Practice Aspects (FY17) • Product Information Report: Amoxicillin (FY17) • Global policy work and partnership with pharmaceutical manufacturers in low resource countries (Presentations) • Local Pharmaceutical Manufacturers in Sub-Saharan Africa and South Asia (Presentations) • Chlorhexidine for Umbilical Cord Care: A new, low-cost intervention to reduce newborn mortality (FY16) • Production Strategy: 7.1% Chlorhexidine Digluconate for Umbilical Cord Care (FY15) Monographs • Chlorhexidine Gel • Zinc Sulfate Tablets • Screening Methods: • Minilab Supplement 2016 • Benzathine benzylpenicillin • Benzylpenicillin sodium or potassium • Gentamicin • Procaine benzylpenicillin • Minilab Supplement 2017 • Chlorhexidine Gel

Core NTD	• Program Overview • Monitoring & Evaluation Plan • Quarterly Progress Tables • Work Plans Documents • Common Technical Document • Data Integrity in GXPs
Core TB	• Program Overview • Monitoring & Evaluation Plan • Quarterly Progress Tables • Work Plans Technical Documents • Product Information Report: Rifapentine (FY17) • Increasing the Supply of Anti-TB Medicines through Market Shaping Approaches: The Case of Kanamycin (Technical Brief) • Cleaning Validation with Risk Assessment (FY17)

B. Other Documents and Websites

New Partnership for Africa's Development (NEPAD). <http://www.nepad.org>

PQM. <http://www.usp.org/global-health/promoting-quality-medicines>.

USAID's Vision for Health Systems Strengthening, 2015-2019. <https://www.usaid.gov/what-we-do/global-health/health-systems/usaid-vision-health-systems-strengthening>

USAID's Automated Directives System (ADS) Function Series 200 – Programming Policy, ADS 201 – Program Cycle Operational Policy. Partial Revision Date: 10/05/2017.

WHO. 2009. Systems Thinking for Health Systems Strengthening. <http://www.who.int/alliance-hpsr/systemsthinking/en/>

WHO. 2017. Global Surveillance and Monitoring System for substandard and falsified medical products. November 2017.

<http://www.who.int/medicines/regulation/ssffc/publications/gsms-report-sf/en/>

WHO. 2017. A study on the public health and socioeconomic impact of substandard and falsified medical products. November 2017.

<http://www.who.int/medicines/regulation/ssffc/publications/se-study-sf/en/>

C. People Interviewed

United States Pharmacopeial (USP) Convention	
Ron Piervincenzi	CEO, USP
Emily Kaine	Senior Vice President, GPH, USP
Tony Lakavage	Senior Vice President, Global External Affairs, USP
Kate Bond	Vice President, International Regulatory Affairs
Mike Levy	Vice President and Head of Quality Institute, USP
Yared Habtegiorgis	Senior Manager, GPH Finance & Administration, USP
Naoko Otani	Senior Director, GPH Operations
Gersande Chavez	Senior Director, GPH Partnerships, Growth & Learning
Feseha Tesema	Senior Manager, Monitoring & Evaluation
PQM HQ	
Jude Nwokike	Director, PQM
Lawrence Evans	Deputy Director, Country & Core Programs
Paul Nkansah	Deputy Director, Technical Support Team
Donnel Charles	Senior Manager, Laboratory Services
Allan Hong	Senior Manager, Manufacturing Services
Elaine Yuan	Senior Program Manager
Latifa El-Hadri	Senior Program Manager

Mustapha Hajjou	Senior Program Manager
Chinwe Owunna	Principal Program Manager
Victor Pribluda	Principal Program Manager
Timothy Nwogu	Manager, Africa Programs
Archil Salakaia	Manager, Core & CIS Programs
Teferi Bedane	Senior GMP Specialist
Jenny Derry	Program Manager
USAID/BGH/OHS	
Kelly Saldana	Director, Office of Health Systems
Beth Drabant	Deputy Director, OHS
Bob Emrey	Lead Health Systems Specialist, OHS
Anthony Boni	Pharmaceutical Management Consultant
Tobey Busch	Senior Pharmaceutical Management Advisor, OHS
Lisa Ludeman	Senior Pharmaceutical Management Advisor, OHS
Thomas Chiang	GH/ID/TB — Pharmaceuticals TA
Penny Smith	GH/ID/NTD — PQM POC
Helen Petach	GH/MCH — Lead PQM/maternal health POC
Deborah Armbruster	GH/MCH — Maternal health TA
Helen Petach	GH/MCH — Maternal health TA
Malia Boggs	GH/MCH — Child health POC
Jennifer Wray	GH/ID/PMI — Division Chief
Lisa Hare	GH/ID/PMI
ETHIOPIA COUNTRY VISIT	
Hailu Tadege	Chief of Party, Ethiopia
Hana Sinkie	Senior Operations Manager
Zelalem Sahile	Senior QA/QC Manager
Dawit Gatchew Abera	M&E Specialist
Keith Hummel	USAID Ethiopia HSS Team Lead
Bikila Bayissa	FMHACA. Deputy Director, PQC Directorate
Yehulu Deneke	FMHACA Director General
Habtamu Beyene	FMHACA Director, Directorate of Registration & Licensing
Kider Tahir	WHO Pharma Coordinator
Mengisteab Weldearegay	WHO EDM consultant

Dr. Ephrem Engidawork	Dean, School of Pharmacy AAU
Prof. Tsige Gebremariam	General Manager Regional Bioequivalence Center, School of Pharmacy AAU
Tegegne Aklilu	Health QA/QC, Cadila Pharmaceuticals
Abayneh Tilaye	Production Manager, Cadila Pharmaceuticals
Regi John	Technical Health, Cadila Pharmaceuticals
Marasi Mwencha	Country Program Director , AIDS-FREE (JSI)
NIGERIA COUNTRY VISIT	
Chimezie Anyakora	PQM Chief of Party, Nigeria
Ben Nwosu	PQM Operations Manager
Adebola Adekoya	PQM QA/QC Specialist
Mopa Esuga	PQM GMP Specialist
Ngozi Isiguzo	PQM M&E Coordinator
Emmanuel A. Ogwuche	USAID Nigeria PQM Activity Manager, Logistics & Commodities Program Manager, Health, Population & Nutrition Office
Laura McGough	USAID Nigeria Health Systems Strengthening/Strategic Information Team Lead, Health, Population and Nutrition Office
Adebayo Samson	NAFDAC. Director: Planning Research and Statistics
B. Olarinwa Yusuf	NAFDAC. Deputy Director: Technical Services
Monica Eimunjeze	NAFDAC. Director: NAFDAC DER
Titilope Owolabi	NAFDAC. Director: AFDAC R&R
Yetunde Oni Ag	NAFDAC. Director General
Ali Ibrahim	NAFDAC. Director of Pharmacovigilance/PMS
Oluwabamiwo Abosede	NDQCL. Deputy Director/Head of Lab – Kaduna
Victor Abiola	NDQCL. Deputy Director/ Head of Lab Yaba
Colette Ifudu	NDCQL. QA Manager — Yaba Lab
Falana Abiodun	Director Laboratory Services
Gamaniell Karniyus	NIPRD. Director General
Kenny Otto	Deputy Director, GHSC-PSM (Chemonics)
Lawal Mashood Oluku	Director: Food and Drugs Services Federal Ministry of Health (FMOH)
Zainab Sheriff	FMOH Head of Traditional Medicine
Mr. Mubarak Chuku	Head of Food, Water , Chemical and Cosmetics Safety
Olubukola Ajai	Head of Drug & Vaccine Development
Okey Akpa	Chairman: Pharmaceutical Manufacturers Group of the Manufacturers Association of Nigeria (PMG-MAN)

Tony Idoko	Director, Planning Research and Stats at the Pharmacists' Council of Nigeria (PCN)
Hamzat Tayo	National Professional Officer Partnership For Transforming Health Systems II, WHO
Ikenna Orakwue	CHI Pharmaceuticals
Shola Akande	General Manager, Drugfield Pharmaceuticals
Nmaka Tijani	RA/QA manager, Fidson Pharmaceuticals
INDONESIA FIELD VISIT	
Christopher Raymond	Chief of Party, Indonesia
Eddy Bahfen	PQM Senior Operations Manager
Yenny Francisca	PQM Senior QC Specialist
Butet Manurung	PQM GMP Specialist
Jonathan Ross	USAID Indonesia Health Director
Handiyanti Handiyanti	USAID Indonesia Health Systems
Rajeev Patel (Elijah)	USAID Indonesia PQM Activity Manager, Drug Quality Adviser
Dra. Nurma Hidayati	BPOM Deputy of Therapeutic Products and Narcotics, Psychotropic and Addictive Substance Control
Dra. Atiek Supardiati	BPOM Head of National Quality Control Laboratory for Drug and Food (PPOMN)
Dra. Togi J. Hutajulu	BPOM Director of Drug and Biological Products Evaluation
I Gusti Ngurah Bagus Kusuma Dewa	BPOM Director of Production Control of Therapeutic Product and Household Product
Dra. Ati Setiawati	BPOM Head of Therapeutic Product and Hazardous Substances Division (PPOMN)
Dra. Dewi Prawitasari	BPOM Head of Balai Besar POM DKI Jakarta Provincial QC lab (Balai Besar/Balai POM)
Dra. Endang Widowati	BPOM Head BBPOM Denpasar Provincial QC lab (Balai Besar/Balai POM)
Dra. Srisurianyati	Technical Manager of BBPOM Denpasar, Provincial QC lab (Balai Besar/Balai POM)
Dra. Dyah Ariyani Yuningsih	Technical Manager of BBPOM Jayapura, Provincial QC lab (Balai Besar/Balai POM)
Lukas Dosonugroho	Technical Manager of Balai POM Manokwari, Provincial QC lab (Balai Besar/Balai POM)
Dra. Triya Novita Dinihari	MOH Section Head of Sub-Directorate of HIV AIDS and Sexually Transmitted Infections
Khairudin	Plant Manager, PT Sanbe Farma
Jepen Nugraha	Plant Manager, Kimia Farma
Mimi Yosiani	Regulatory Manager, PT Kalbe Farma

Ariestiana Adjii	Head of Quality Assurance, PT Kalbe Farma
Dra. Barokah Sri Utami	President Director, PT Phapros
Raditya Prima Istiaji	Manager Analytical Development, PT Phapros
Effi Setiawati	Equilab International (contract research organization)
Ariningsun Puri Cinantya	Pharma Metric Lab (contract research organization)
Dr. Agnes Gebhard	Chief of Party, Challenge TB/ Country Representative KNCV CTB
Caroline Francis	Country Representative, (LINKAGES Project) FHI 360
Global and Regional Stakeholders	
Sue Hill	WHO. Director, Department of Essential Medicines and Health Products
Mike Ward	WHO; Coordinator, Regulatory Systems Strengthening, Department of Essential Medicines and Health Products
Michael Deats	WHO; Group Lead, SSFFC Medical Products, Department of Essential Medicines and Health Products
Deus Mubangizi	WHO; Coordinator of the Prequalification Team, Department of Essential Medicines and Health Products
Alain Prat	Quality Assurance Specialist at The Global Fund To Fight AIDS, Tuberculosis and Malaria
Andreas Seiter	Senior Health Specialist – Pharmaceuticals Health, Nutrition and Population The World Bank
Brenda Waning	Chief, Global Drug Facility, Stop TB Partnership at UNOPS
Andre Zagorski	Previous: Operations Manager, GDF; Current: Senior Principal Technical Advisor at Management Sciences for Health
Kaspars Lunte	Team Leader MDR-TB Medicines supply, Global TB Drug Facility
Andy Stergachis	Professor of Pharmacy & Global Health Associate Dean, School of Pharmacy Director, Global Medicines Program
Margareth Sigonda	AMRH Programme Coordinator
Aggrey Ambali	Coordinator of Biosciences and the Science and Technology Division of NEPAD
Richard Jaehnke	Global Pharma Health Fund (GPHF); Project Management
Paul Newton	Mahosot Hospital VTE Laos; Coordination and Clinical Lecturer, Microbiology Laboratory
Stanley Sonoiya	East African Community (EAC); Principal Health Officer
Muhammad Zaman	Howard Hughes Medical Institute Professor, Department of Biomedical Engineering and International Health
Veronika J. Wirtz	Boston University, Department of Global Health, School of Public Health
Pat Lukulay	Former, Vice President, Global Public Health at USP

ANNEX IV. RESOURCES FOR MAPPING AND MEASURING RESOURCES, THEORY OF CHANGE, AND SYSTEMS THINKING

MAPPING AND MEASURING OUTCOMES

The resources listed below are recommendations to help map and measure outcomes that are non-linear in fashion. These approaches do not require an evaluation expert and in most cases can be undertaken by the M&E team. The [Better Evaluation Initiative](#) is a highly regarded M&E resource. The website is targeted to non-M&E experts, and provides clear, jargon free information.

Three approaches to outcome mapping and measurement that are salient to PQM's work are outlined below.

1. Most Significant Change (MSC)

The Most Significant Change technique has gained increased popularity as a way to measure outcomes. MSC uses a “context-mechanism-outcome” (CMO) configuration as a way for organizations to identify and then map the context and processes that lead to outcomes. The technique is particularly helpful for organizations to “tell the story” of their work. This technique is often used by organizations to measure complex interventions including health system strengthening.

Resources for more information:

Lennie J. The Most Significant Change technique A manual for M&E staff and others at Equal Access. Feb 2011.

https://www.betterevaluation.org/sites/default/files/EA_PM%26E_toolkit_MSC_manual_for_publication.pdf

Example of MSC: [Suaahara MSC stories](#). USAID. No date.

2. Realist Evaluation (RIE)

Realist evaluation is a useful approach to not only map outcomes but also measure outcomes. The value of RIE is that it captures the context of implementation, specifically the *why* and *how* the intervention worked or did not work. These results can support scale-up and/or replication in other settings. The results from RIE studies also lend well to knowledge-translation.

Westhorp G. [Realist Impact Evaluation: An Introduction](#). Overseas Development Institute. Sept 2014.

3. Beneficiary Assessment (BA)

A Beneficiary Assessment is highly salient to the PQM program. As the name implies the approach relies on the beneficiary of the assistance to assess the value of activities by the recipient. It relies on end-user to determine what are the important outcomes rather than the implementer. The approach is used in many disciplines including health system strengthening.

Salmen L. [Beneficiary Assessment: An Approach Described](#). World Bank. August 2002.

4. Theory of Change/Pathway of Change

A theory/pathway of change outlines the predicted process of change and the mediators that may influence those processes and subsequent outcomes. Theoretical approaches are at the heart of

Implementation Science, which is the “science” of why implementation did or did not work, and the strength of implementation.

1. [Theory of Change and Program Design](#). IPA. Feb 2016.
2. James R M Hargreaves, Catherine Goodman, Calum Davey, et al. [Measuring implementation strength: lessons from the evaluation of public health strategies in low- and middle-income settings](#). Health Policy and Planning, Volume 31, Issue 7, 1 September 2016, Pages 860–867
3. Nilsen P. [Making sense of implementation theories and frameworks](#). Implementation Science. April 2015; 10:53.
4. [Develop Programme Theory](#). Better Evaluation resource.
5. Paina L, Wilkinson A, Tetui M, Ekirapa-Kiracho E, et.al. [Using Theories of Change to inform implementation of health systems research and innovation: experiences of Future Health Systems consortium partners in Bangladesh, India and Uganda](#). Health Research Policy and Systems 2017, 15 (Suppl 2):109.

5. Systems Thinking

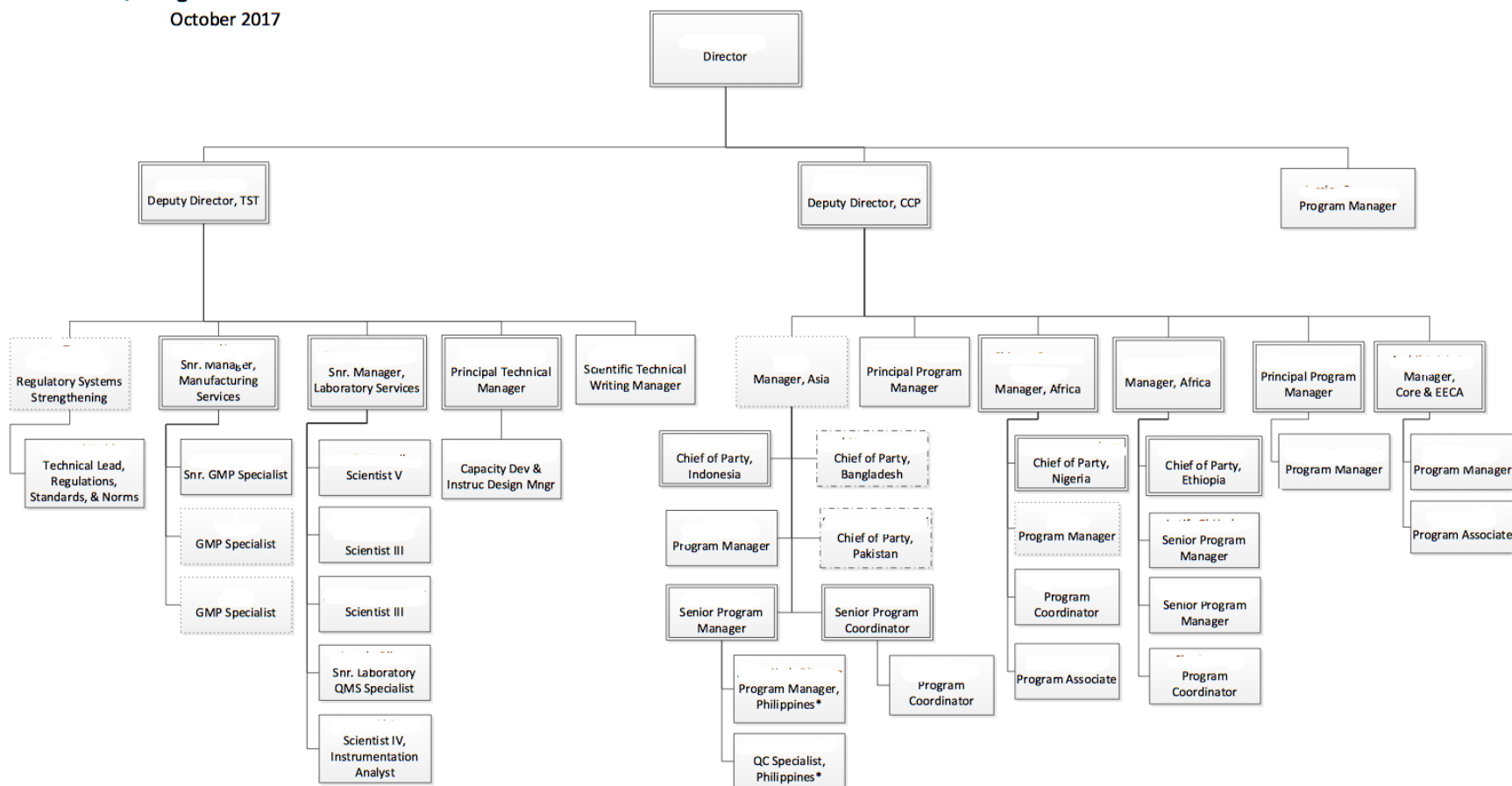
The resources below are helpful starting points to learn more about the basics of systems thinking and health system strengthening measurement. The resources also include examples.

1. Don de Savigny and Taghreed Adam (Eds). [Systems thinking for health systems strengthening](#). Alliance for Health Policy and Systems Research, WHO, 2009.
2. Diana M, Yeager V, Hotchkiss D. [Health Systems Strengthening – A Literature Review. Measure Evaluation](#). Sept 2017.
3. Bennett S, Mahmood S.S., Edward A, et.al. [Strengthening scaling up through learning from implementation: comparing experiences from Afghanistan, Bangladesh and Uganda](#). Health Res Policy Syst. 2017; 15(Suppl 2): 108.
4. Adam T. [Advancing the application of systems thinking in health](#). Health Research Policy and Systems. 2014;12:50.
5. [Advancing the Application of Systems Thinking in Health](#). Adam T (ed.). Alliance for Health Policy and Systems Research, World Health Organization. 2014. *Articles part of a thematic series of Health Research Policy and Systems, BMC.

ANNEX V. PQM MANAGEMENT STRUCTURE

PQM Organizational Chart

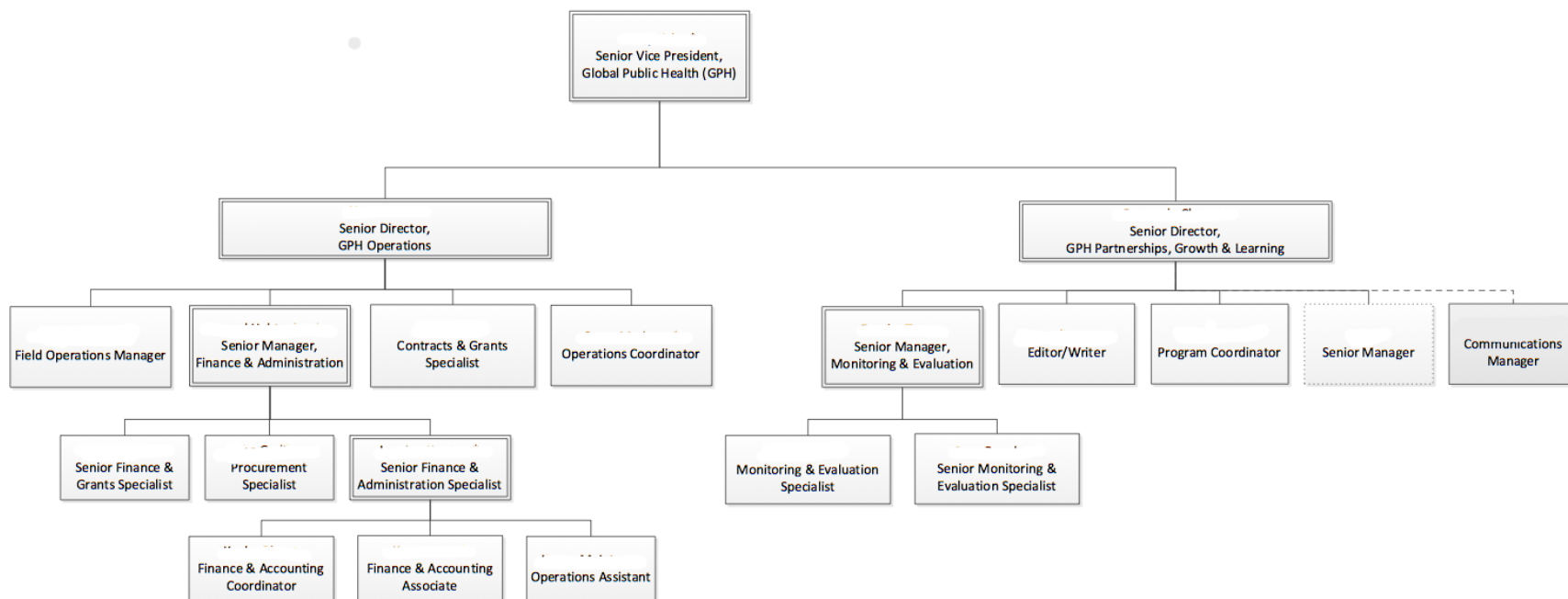
October 2017



* Position transitioned to USP-GPH on October 16, 2017

PQM Support Functions Organizational Chart

September 2017

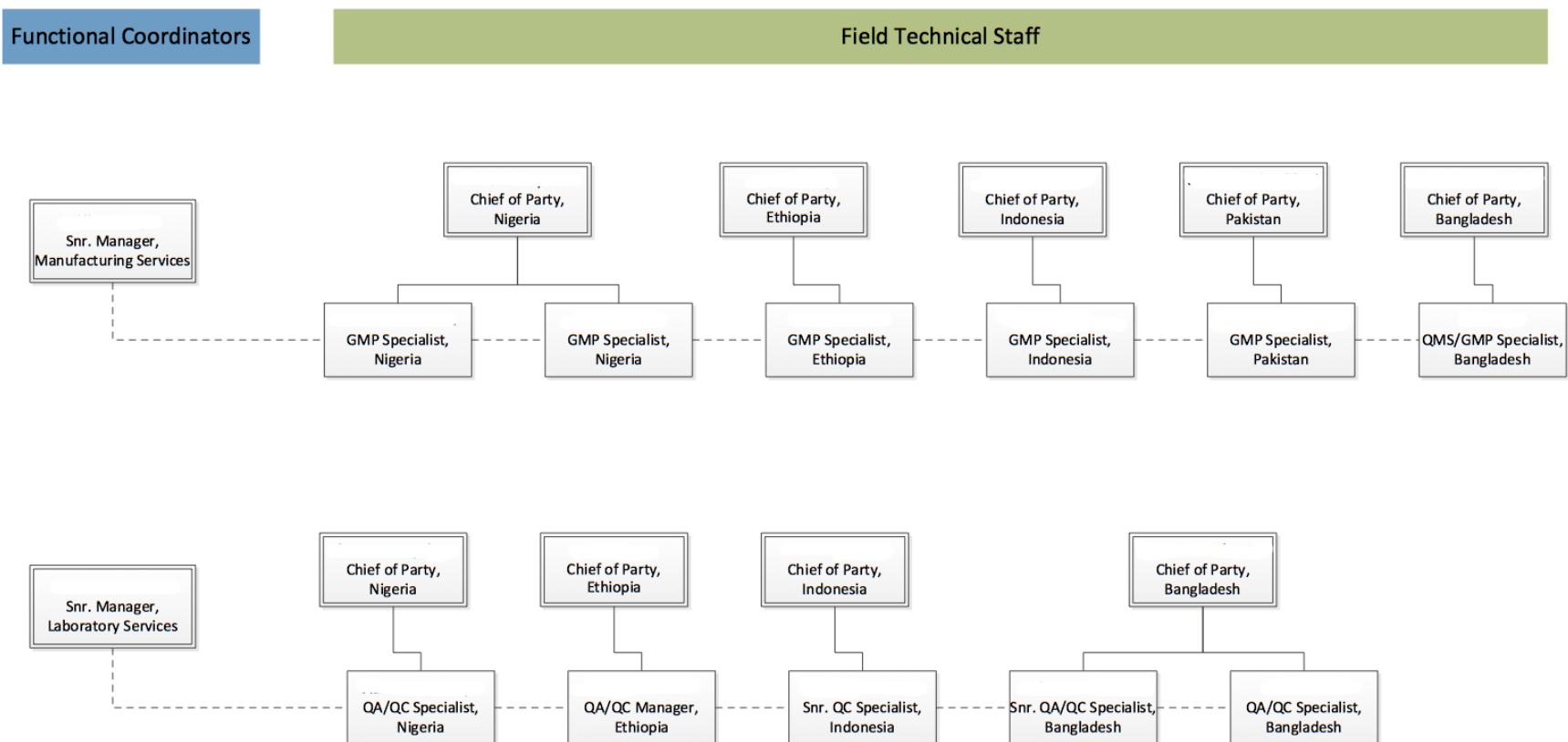


* Indicates position fully funded by USP-GPH

PQM Functional Relationships

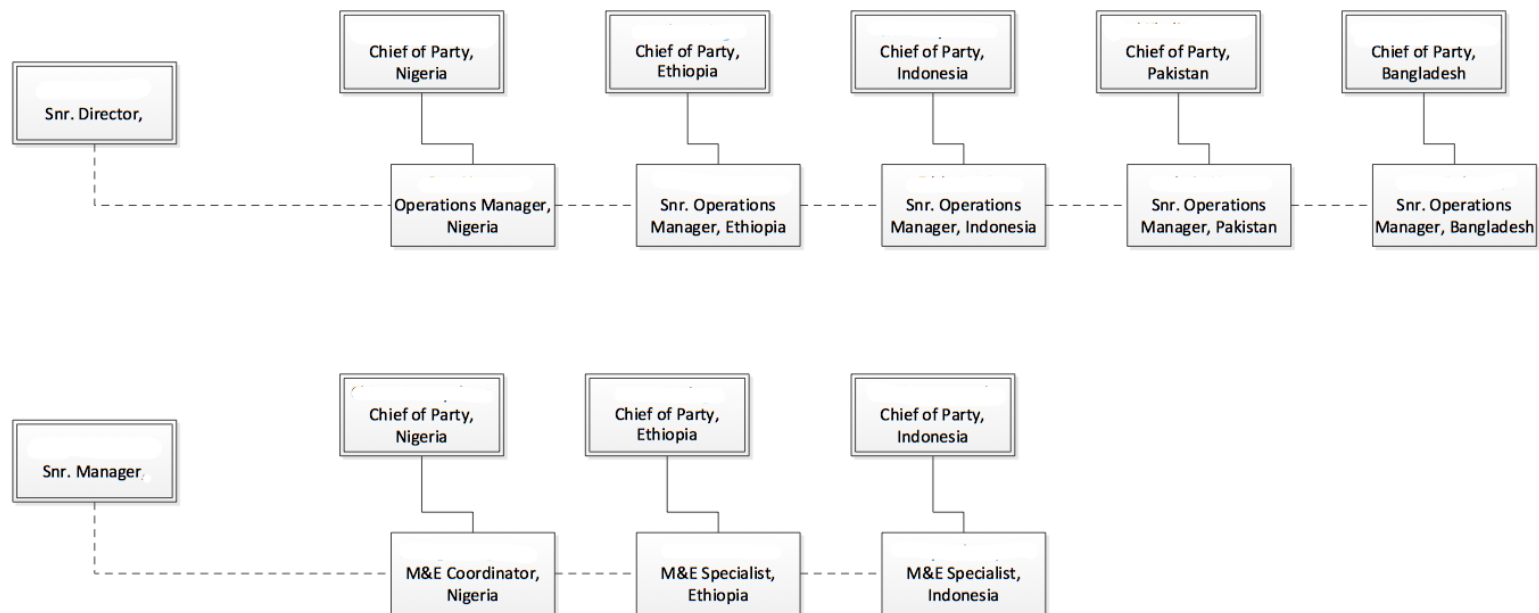
October 2017

PQM uses functional relationships to ensure a harmonized approach in various technical areas, consistently implement defined policies and process across functions, increase collaboration across geographies, and share best practices. Four functional groups have been created, which are led by Functional Coordinators, outlined in the schematic below.



Functional Coordinators

Field Technical Staff



ANNEX VI. DISCLOSURE OF ANY CONFLICTS OF INTEREST

GLOBAL HEALTH PROGRAM CYCLE IMPROVEMENT PROJECT

USAID NON-DISCLOSURE AND CONFLICTS AGREEMENT

USAID Non-Disclosure and Conflicts Agreement- Global Health Program Cycle Improvement Project

As used in this Agreement, Sensitive Data is marked or unmarked, oral, written or in any other form, "sensitive but unclassified information," procurement sensitive and source selection information, and information such as medical, personnel, financial, investigatory, visa, law enforcement, or other information which, if released, could result in harm or unfair treatment to an individual or group, or could have a negative impact upon foreign policy or relations, or USAID's mission.

Intending to be legally bound, I hereby accept the obligations contained in this Agreement in consideration of my being granted access to Sensitive Data, and specifically I understand and acknowledge that:

1. I have been given access to USAID Sensitive Data to facilitate the performance of duties assigned to me for compensation, monetary or otherwise. By being granted access to such Sensitive Data, special confidence and trust has been placed in me by the United States Government, and as such it is my responsibility to safeguard Sensitive Data disclosed to me, and to refrain from disclosing Sensitive Data to persons not requiring access for performance of official USAID duties.
2. Before disclosing Sensitive Data, I must determine the recipient's "need to know" or "need to access" Sensitive Data for USAID purposes.
3. I agree to abide in all respects by 41, U.S.C. 2101 - 2107, The Procurement Integrity Act, and specifically agree not to disclose source selection information or contractor bid proposal information to any person or entity not authorized by agency regulations to receive such information.
4. I have reviewed my employment (past, present and under consideration) and financial interests, as well as those of my household family members, and certify that, to the best of my knowledge and belief, I have no actual or potential conflict of interest that could diminish my capacity to perform my assigned duties in an impartial and objective manner.
5. Any breach of this Agreement may result in the termination of my access to Sensitive Data, which, if such termination effectively negates my ability to perform my assigned duties, may lead to the termination of my employment or other relationships with the Departments or Agencies that granted my access.
6. I will not use Sensitive Data, while working at USAID or thereafter, for personal gain or detrimentally to USAID, or disclose or make available all or any part of the Sensitive Data to any person, firm, corporation, association, or any other entity for any reason or purpose whatsoever, directly or indirectly, except as may be required for the benefit USAID.
7. Misuse of government Sensitive Data could constitute a violation, or violations, of United States criminal law, and Federally-affiliated workers (including some contract employees) who violate privacy safeguards may be subject to disciplinary actions, a fine of up to \$5,000, or both. In particular, U.S. criminal law (18 USC § 1905) protects confidential information from unauthorized disclosure by government employees. There is also an exemption from the Freedom of Information Act (FOIA) protecting such information from disclosure to the public. Finally, the ethical standards that bind each government employee also prohibit unauthorized disclosure (5 CFR 2635.703).
8. All Sensitive Data to which I have access or may obtain access by signing this Agreement is now and will remain the property of, or under the control of, the United States Government. I agree that I must return all Sensitive Data which has or may come into my possession (a) upon demand by an authorized representative of the United States Government; (b) upon the conclusion of my employment or other relationship with the Department or Agency that last granted me access to

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Sensitive Data; or (c) upon the conclusion of my employment or other relationship that requires access to Sensitive Data.

9. Notwithstanding the foregoing, I shall not be restricted from disclosing or using Sensitive Data that:
- (i) is or becomes generally available to the public other than as a result of an unauthorized disclosure by me; (ii) becomes available to me in a manner that is not in contravention of applicable law; or (iii) is required to be disclosed by law, court order, or other legal process.

ACCEPTANCE

The undersigned accepts the terms and conditions of this Agreement.

	<u>8/17/2017</u>
Signature	Date
<u>MARIA A. MIRALLES</u>	<u>CONSULTANT</u>
Name	Title

GLOBAL HEALTH PROGRAM CYCLE IMPROVEMENT
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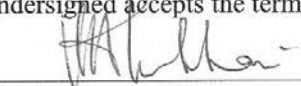
Sensitive Data; or (c) upon the conclusion of my employment or other relationship that requires access to Sensitive Data.

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ACCEPTANCE

The undersigned accepts the terms and conditions of this Agreement.

Signature


Vincent I. Thonkhan

Date

10-2-17

Name

Title

MD

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PROJECT

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ACCEPTANCE

The undersigned accepts the terms and conditions of this Agreement.

Signature	EunMi	디지털 서명 자EunMi Kim	Date
Name	Kim	날짜: 2017.08.25 10:22:12 +09'00'	Aug. 25, 2017/ Consultant Title

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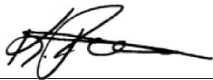
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 - (iii) is required to be disclosed by law, court order, or other legal process.

ACCEPTANCE

The undersigned accepts the terms and conditions of this Agreement.

Signature



Date

Sept 8 2017

Name

Katia Peterson PhD, MPH

Title

Consultant

ANNEX VI. SUMMARY BIOS OF EVALUATION TEAM

Maria A. Miralles, PhD, Team Lead. Dr. Miralles holds a PhD in pharmacy health care administration, an MA in anthropology, and a graduate certificate in gerontology. She has worked with a variety of bilateral and multilateral agencies, private companies, and foundations. She has served as senior pharmaceutical management advisor to USAID's Bureau of Global Health's OHS and has held several senior management and technical positions on key USAID flagship pharmaceutical management programs, including the Rational Pharmaceutical Management Plus and Strengthening Pharmaceutical Systems programs. She has an extensive experience working the design, management, and evaluation of health programs focused on improving access to quality-assured medicines and services for HIV/AIDS, tuberculosis, malaria, and maternal and child health.

Dr. Miralles' role on the evaluation was to provide overall managerial and technical leadership. In collaboration with other team members, she developed the evaluation work plan and participated in the design of the data collection and analysis activities, including questionnaire and survey tool development. She also led field-based data collection in Indonesia, Nigeria, Ethiopia, and Geneva. Dr. Miralles contributed to responses to all the evaluation questions, leading on the responses to Evaluation Questions 2 and 5.

EunMi Kim, Pharmaceutical Regulatory Systems Expert. Ms. EunMi Kim has 19 years' experience as a pharmacist and regulatory affairs specialist. She holds an M.Sc. in health policy and management. She provides technical support in medicine regulatory, policy issues, quality assurance, and technical capacity building as an independent consultant. As a senior technical advisor at Management Science for Health, she worked with Medicine Regulatory Authorities to strengthen regulatory systems in low and middle-income countries. She worked as a regulatory expert in global pharmaceutical companies before joining Management Science for Health.

Her role on the evaluation was to provide technical inputs to the design and planning, with a focus on regulatory policy and technical capacity building. She participated in data collection activities in Indonesia, Nigeria, and Ethiopia by conducting face-to-face interviews with informants. She contributed to analyzing and interpreting data for all the evaluation questions and led Question 1, with focus on NMRAs, NDQCLs, and manufacturing capacity building.

Vincent I. Ahonkhai, MD, FAAP, Global Health Initiatives Specialist. Dr. Ahonkhai is a global health consultant specializing in the research and development, national registration, and access promotion for bio-pharmaceuticals, vaccines, and diagnostics for intervention against communicable diseases in emerging economy countries. He has more than two decades of experience in bench research and academic and clinical medicine as a board-certified pediatrician and specialist in adult and pediatric infectious diseases. He was until recently a senior advisor of global health at the Bill & Melinda Gates Foundation, where his role included executing major grants with global and regional organizations. Prior to that, he served in leadership positions in the pharmaceutical industry as vice president in clinical development, medical affairs, regulatory affairs and product safety, and pharmacovigilance.

On the evaluation, Dr. Ahonkhai participated in stakeholder interviews, data collection, and reporting, with a focus on aspects relating to global partnership operations in low- and middle-income countries. He was the lead on responses to Evaluation Question 4. He also contributed technical input on regulatory affairs, safety surveillance, and pharmacovigilance, particularly in sub-Saharan Africa, as well as perspectives on effective grant-making to support regional and global initiatives.

Katia Peterson, PhD, Evaluation Specialist. Dr. Peterson has more than 15 years' experience designing and implementing research and evaluation studies of health systems strengthening interventions (e.g., human resources for health, supply chain management, and health information systems). Dr. Peterson's core competencies include mixed method process, outcome, and system performance evaluations; programmatic and policy reviews; literature and systematic reviews (including meta-analysis); qualitative and quantitative data analysis; and knowledge translation for evidence-informed decision-making. She has experience working with USAID, multilateral organizations, NGOs, and in-country governments. In addition to her work as a consultant, she is an adjunct faculty member in the School of Public Health at The George Washington University. Dr. Peterson has an MPH in epidemiology and a PhD in public health.

Dr. Peterson's role on the evaluation team was to lead the development of data collection tools and analysis frameworks, data analysis and production of graphics, and co-facilitation of interviews. She was responsible for developing the methods section of the final report and leading the response to Evaluation Question 3. She also contributed to critical reviews of all other questions.

For more information, please visit

<http://ghpro.dexisonline.com/reports-publications>

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